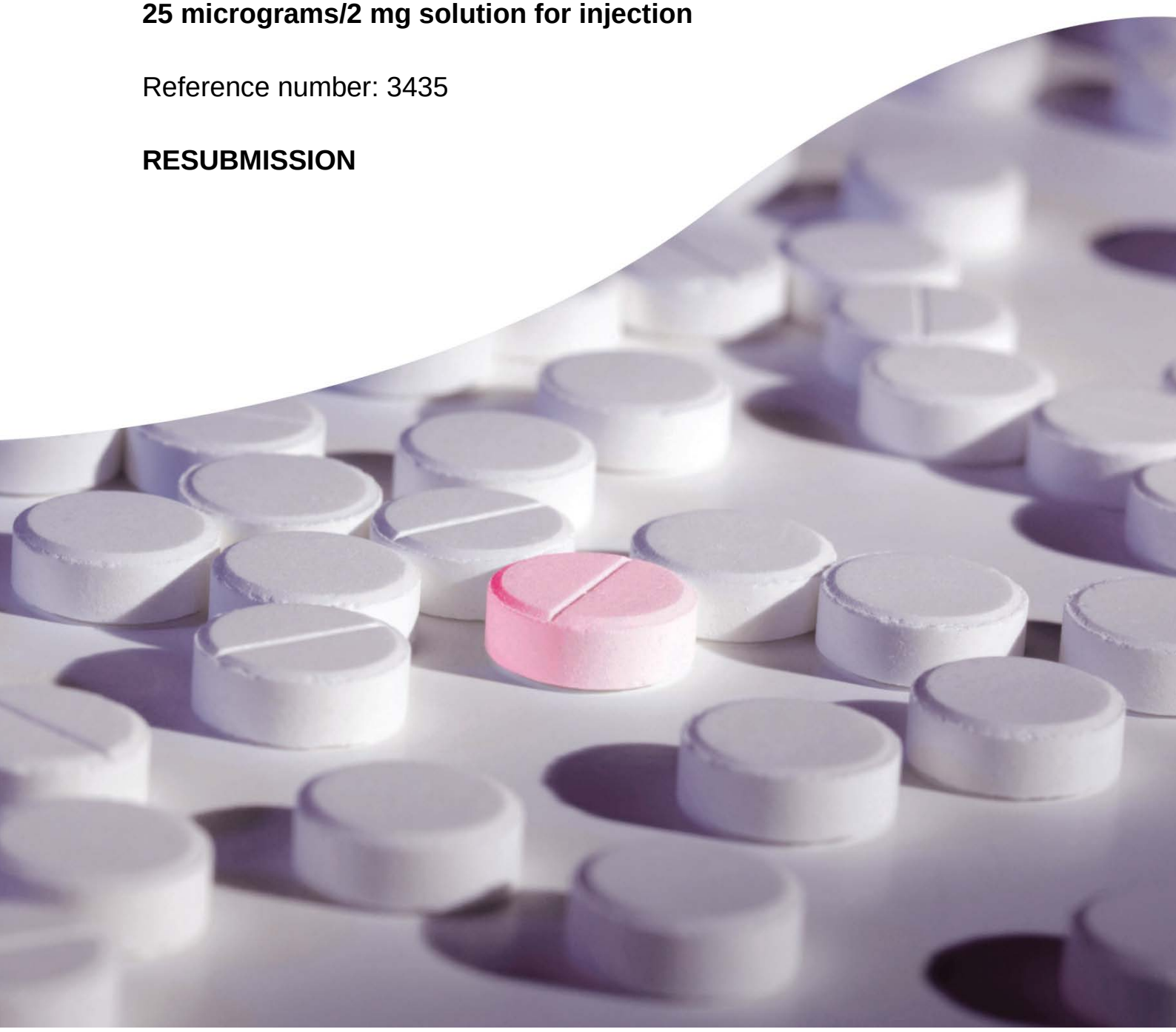
AWTTC
All Wales Therapeutics & Toxicology Centre
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

AWMSG SECRETARIAT ASSESSMENT REPORT

Aviptadil/phentolamine mesilate (Invicorp®)
25 micrograms/2 mg solution for injection

Reference number: 3435

RESUBMISSION



PAMS
Patient Access to Medicines Service
Mynediad Claf at Wasanaeth Meddyginiaethau

This report has been prepared by the All Wales Therapeutics & Toxicology Centre (AWTTC).

Please direct any queries to AWTTC:

All Wales Therapeutics & Toxicology Centre (AWTTC)
University Hospital Llandough
Penlan Road
Llandough
Vale of Glamorgan
CF64 2XX

awttc@wales.nhs.uk
029 2071 6900

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AWMSG Secretariat Assessment Report
Aviptadil/phentolamine mesilate (Invicorp®) 25 micrograms/2 mg solution for injection

This assessment report is based on evidence submitted by Evolan Pharma AB[1].

1.0 PRODUCT DETAILS

Licensed indication under consideration	Aviptadil/phentolamine mesilate (Invicorp®) for the symptomatic treatment of erectile dysfunction in adult males due to neurogenic, vasculogenic, psychogenic, or mixed aetiology[2].
Dosing	Aviptadil/phentolamine is administered by direct intracavernous injection. The recommended dose is 25 micrograms/2 mg (one ampoule). Initial injections of aviptadil/phentolamine must be administered by medically trained personnel, but aviptadil/phentolamine may be injected at home after training. Injection frequency should not exceed once daily or three times weekly[2].
Marketing authorisation date	21 April 2015[2].

2.0 DECISION CONTEXT

2.1 Background

Erectile dysfunction is defined as the persistent inability to attain and maintain an erection sufficient to permit satisfactory sexual performance[3]. Erectile dysfunction affects the physical and/or psychosocial health of sufferers, and may have a significant impact on the quality of life of both sufferers and their partners. Erectile dysfunction is associated with physical causes (such as diabetes mellitus, hypertension and radical prostatectomy), psychological or emotional causes (such as relationship problems or mental health problems), and the use of certain medicines (such as antihypertensive treatments)[3].

When pharmacological therapy is used to treat erectile dysfunction, first-line therapy is usually with oral PDE5 inhibitors (sildenafil, tadalafil, avanafil or vardenafil), or in some cases with vacuum erection therapy[4,5]. Second-line treatments include alprostadil, which can be administered by intracavernous injection, or by intraurethral or topical administration[4,5]. Invicorp® is a combination of 25 micrograms aviptadil and 2 mg phentolamine, administered by intracavernous injection[2]. The company proposes that aviptadil/phentolamine should be considered for use in people with erectile dysfunction that has not responded to oral therapy[1].

The All Wales Medicines Strategy Group (AWMSG) has previously appraised aviptadil/phentolamine for the treatment of erectile dysfunction and issued a non-recommendation for this indication[6]. An updated AWMSG submission has been made for aviptadil/phentolamine which includes a strengthened cost-effectiveness analysis[1].

2.2 Comparators

The comparator included in the company submission was alprostadil, administered as intracavernous injection (Caverject®).

2.3 Guidance and related advice

- European Association of Urology. Guidelines on male sexual dysfunction: erectile dysfunction and premature ejaculation (2016)[5].
- British Society for Sexual Medicine. Guidelines on the management of erectile dysfunction (2013)[4].
- AWMSG. All Wales guidance on prescribing for erectile dysfunction (2012)[7].

AWMSG has previously issued a non-recommendation for the use of aviptadil/phentolamine (Invicorp®) for the treatment of erectile dysfunction, stating that the applicant company did not present sufficiently robust clinical and economic analyses to gain approval[6].

AWMSG has previously issued a recommendation for the use of avanafil (Spedra®)[8].

3.0 SUMMARY OF EVIDENCE ON CLINICAL EFFECTIVENESS

The company highlights evidence from one study comparing aviptadil/phentolamine with alprostadil, and two studies comparing aviptadil/phentolamine with placebo[1]. As the latter studies do not include an active comparator, only safety outcomes from these studies will be discussed in this report.

3.1 Comparative efficacy: study VP 007

This was an open-label, multicentre randomised crossover study designed to compare efficacy and tolerability of aviptadil/phentolamine and alprostadil, and to evaluate patient preference for these treatments[9]. Inclusion criteria were patients with erectile dysfunction for at least one year who were in a stable heterosexual relationship and over 18 years of age. Patients received aviptadil in combination with phentolamine; each at a range of doses (12.5 or 25 micrograms of aviptadil and 0.5, 1.0 or 2.0 mg of phentolamine, respectively). Patients received alprostadil at doses of 5–20 micrograms. All treatments were self-administered[9].

The study consisted of two phases[9]. Phase 1 was a dose-finding phase, used to establish the doses of aviptadil/phentolamine and alprostadil required to achieve a grade 3 erection in each patient. Patients who did not achieve an adequate response to either treatment were not eligible for phase 2 of the study. In phase 2, the comparative phase, patients received each treatment at the dose at which they had achieved a response in phase 1. Each patient was issued with four doses of aviptadil/phentolamine presented as ampoules and four doses of alprostadil presented as powder for injection; the order in which patients received these was randomised. Additionally, each patient received four doses of aviptadil/phentolamine presented in an auto-injector, for use after completion of the other two treatments. In both phases, efficacy was determined using information provided by patients, which had been recorded in a diary[9].

In phase 1, 187 patients received treatment[9]. Significantly fewer patients achieved a grade 3 erection after treatment with aviptadil/phentolamine (137 [73%]) than after treatment with alprostadil (155 [83%]). Phase 2 included 107 patients, and results were reported in terms of the total number of injections: the percentage of injections resulting in a grade 3 erection were 83%, 84% and 85% with alprostadil, aviptadil/phentolamine ampoules and aviptadil/phentolamine auto-injector, respectively. Patient treatment preference was reported for 51 patients in phase 1 and 67 patients in phase 2. In both phases, significantly more patients preferred one of the aviptadil/phentolamine

preparations over alprostadil. In phase 2 of the study, 73% of patients preferred the aviptadil/phentolamine auto-injector preparation (not currently licensed in the UK), whilst 19% preferred the licensed aviptadil/phentolamine ampoules preparation and 8% preferred alprostadil[9].

3.2 Comparative safety

The applicant company highlighted adverse events with aviptadil/phentolamine as listed in the summary of product characteristics (SPC)[2] and based on two placebo-controlled randomised studies (343 patients included across the two studies)[10,11]. According to the SPC, approximately 10% of patients experience adverse reactions to aviptadil/phentolamine[2]. The most common adverse events are bruising at the injection site and flushing[2].

The company submission notes that in study VP 007 significantly fewer patients in the comparative phase reported pain with aviptadil/phentolamine ampoules than with alprostadil (3 versus 28 reports of pain per 100 injections/patient, respectively)[1]. In the comparative phase, 49 (46%) and 32 (30%) patients reported an adverse event with alprostadil and aviptadil/phentolamine ampoules, respectively; 15 (14%) and 6 (6%) patients respectively reported a moderate or severe adverse event. In the earlier dose-finding phase, 86 (46%) and 57 (30%) of patients reported an adverse event with alprostadil and aviptadil/phentolamine ampoules, respectively; 23 (12%) and 8 (4%) of patients respectively reported a moderate or severe adverse event. Although aviptadil/phentolamine was associated with significantly fewer incidences of pain compared with alprostadil, there were significantly more incidences of facial flushing with aviptadil/phentolamine (3 versus 17 cases per 100 injections, respectively, $p < 0.001$). No cases of priapism were reported with either treatment[1,9].

3.3 AWTTC critique

- The company proposes that aviptadil/phentolamine should be considered for use in people with erectile dysfunction that has not responded to oral therapy. Their submission therefore focuses on comparing aviptadil/phentolamine with Caverject®, an intracavernous injection of alprostadil that is recommended for second-line use by clinical guidelines[4,5]. Alprostadil is also available as a cream[12] or urethral stick[13], but the company has not included these alternative alprostadil preparations as comparators. Furthermore, the clinical effectiveness evidence presented is not specific to this population: inclusion criteria for VP 007 did not require patients to have been treated previously for their erectile dysfunction.
- In their submission, the company briefly summarises the results of VP 007 as demonstrating that the efficacy of aviptadil/phentolamine is similar to alprostadil. This conclusion is based on results from the comparative phase of the study (phase 2). However, the comparative phase excluded patients who did not respond to treatment with either aviptadil/phentolamine or alprostadil. Results of the earlier dose-finding phase of the study, which included all patients recruited into the study, show that significantly fewer patients achieved a grade 3 erection with aviptadil/phentolamine than with alprostadil[9]. The company notes that the first phase of the study was primarily a dose-response phase and would not have been optimally conducive to a natural sexual response. However, phase 2 of the study also reported differences in the adverse event profiles of the two treatments. It is therefore unclear whether the clinical effectiveness of aviptadil/phentolamine is equivalent to alprostadil.
- In study VP 007, patients received a range of doses of aviptadil and phentolamine (12.5 or 25 micrograms and 0.5, 1.0 or 2.0 mg, respectively), either prepared from ampoules or administered in an auto-injector. Therefore, not all patients received aviptadil/phentolamine as the licensed (25 micrograms/2 mg) dose and formulation. Similarly, patients received alprostadil at doses of 5–20 micrograms, and although the SPC states that the

majority of patients achieve a satisfactory response within this dose range, doses of up to 60 micrograms can be used[14]. Therefore, it is unclear whether the doses used in VP 007 are fully representative of clinical practice for either medicine.

- Study VP 007 used two aviptadil/phentolamine preparations, only one of which (ampoules) is licensed in the UK. The company claim that results of this study demonstrate a significant patient preference for aviptadil/phentolamine over alprostadil. However, as discussed in Section 3.1, in phase 2 of the study the majority of patients preferred the unlicensed aviptadil/phentolamine auto-injector preparation.
- The company submission has a number of limitations; only brief details are provided in support of comparative safety and efficacy, and potential methodological limitations concerning the pivotal study are not explored. The study is described as a randomised crossover study, but no detail is reported of how patients crossed over from one treatment to another. Patients were only eligible for the comparative phase of the study if they achieved a grade 3 erection with both study treatments, meaning that this phase of the study is likely to overestimate the effectiveness of both treatments. Furthermore, 130 patients completed phase 1, but only 107 patients started phase 2. Reasons for patients dropping out of the study are not explained. Grade 3 erections are reported per patient in phase 1 but per injection in phase 2; the reason for this discrepancy is also not explained, and the total number of patients for whom results were available in phase 2 is not clear.

4.0 SUMMARY OF THE EVIDENCE ON COST-EFFECTIVENESS

4.1 Cost-effectiveness evidence

4.1.1 Context

The company submission[1] includes a cost minimisation analysis (CMA) comparing intracavernous injection of aviptadil/phentolamine (Invicorp®) 25 micrograms/2 mg with alprostadil (Caverject® dual chamber) 20 micrograms in the treatment of adult males with erectile dysfunction attributable to neurogenic, vasculogenic, psychogenic, or mixed aetiology. The proposed place in therapy is treatment of erectile dysfunction that has not responded to oral therapy. This positioning is in line with European Association of Urology Guidelines[5] and has been validated by company-sought clinical expert opinion. The company state that a CMA approach is justified because aviptadil/phentolamine 25 micrograms/2 mg is regarded as equally efficacious to alprostadil 20 micrograms (based on evidence from VP 007, and supported by clinical expert opinion) and because no appropriate health-related quality of life data were collected in the pivotal trial[9].

The CMA adopts a NHS Wales/Personal and Social Services perspective and a one year time horizon. Efficacy data used to inform the CMA are taken from study VP 007, which is described in detail in Section 3.1. The inclusion criteria for this study did not require patients to have been treated previously for their erectile dysfunction (i.e. patients could be naive to PDE5 inhibitors). Data on the risk of experiencing priapism and penile fibrosis have been taken from the SPC for alprostadil[15] and used in the model. Based on clinical expert advice, it is assumed that there is no risk of these two adverse events with aviptadil/phentolamine. Data on the incidence of other grade 3 and 4 adverse events are taken from study VP 007. Whilst the risk of experiencing these adverse events is acknowledged in the model, no costs have been apportioned to them, and therefore they are effectively omitted from the CMA.

Costs included in the model are drug acquisition, and administration costs, and cost of treatments associated with priapism and penile fibrosis. Drug acquisition costs are sourced from the Monthly Index of Medical Specialities (MIMS)[16]. Drug administration

costs are informed by NHS Reference Costs[17]. The costs associated with priapism and penile fibrosis are taken from NHS Reference costs[17] and the Department of Health electronic market information tool (eMit)[18]. It is assumed that aviptadil/phentolamine treatment requires one consultant appointment, for instructions on use, whereas alprostadil requires titration over three consultant visits to avoid risk of priapism. It is also assumed that patients will inject on average once weekly, as per clinical expert advice.

One-way sensitivity analyses and scenario analyses have been conducted to explore the impact of altering the values of key parameters and structural assumptions on incremental cost.

4.1.2 Results

The results of the base case analyses are presented in Table 1. The unit costs of aviptadil/phentolamine 25 micrograms/2 mg and alprostadil 20 micrograms dual chamber are identical (£9.50 per injection). However, there is a difference in drug acquisition costs in the first year of administration, resulting in a saving of £14.70 from the use of aviptadil/phentolamine. This saving arises from differences in titration requirements. After the first year of treatment, subsequent acquisition costs are identical for the two treatments. Acquisition cost savings combined with those attributed to drug administration and adverse events produce an overall reported cost saving of £283.93 per patient. The majority of costs savings are attributed to differences in administration costs.

Table 1. Key results of the base case analyses

Cost	Aviptadil/phentolamine	Alprostadil	Difference
Drug acquisition (including titration doses)	£505.20	£519.90	−£14.70
Drug administration	£122.00	£322.00	−£200.00
Adverse events	£0	£69.23	−£69.23
Total Cost	**£627.20**	**£911.12**	**−£283.93**

One way sensitivity analyses show that the two most influential parameters in the model are the number and cost of appointments required for a patient taking alprostadil. The number of 10 microgram and 20 microgram chambers of alprostadil required for titration also has some influence. However, in all instances, use of the lower and upper bound of 95% confidence intervals results in cost savings.

The scenario analyses explore the effects of alternative discount rates, alprostadil doses, number of alprostadil consultant appointments, priapism rates with alprostadil, and time horizon. All of these analyses result in incremental cost savings. Those having the greatest influence are detailed in Table 2.

Table 2. Key results of the scenario analyses

Scenarios	Aviptadil/ phentolamine	Alprostadil	Difference	Plausibility
Dosing of alprostadil: a) IMS data dosing (i.e. not all patients receive 20 micrograms) b) Prescription Cost Analysis dosing	a) £627.20 b) £627.20	a) £1,074.64 b) £1,030.20	a) −£447.44 b) −£403.00	a) These prescription data are for the whole of the UK and are not Wales specific, and relate to the period Q1 2013 to Q4 2014. b) These data are for England only, but were collated in 2016. There is no evidence to suggest that dosing in Wales is likely to be different to other parts of the UK. Welsh prescribing data supports the proposition that a variety of doses are being prescribed. Therefore, these scenarios are plausible alternatives to the base case.
One additional alprostadil consultant appointment (i.e. total of four)	£627.20	£1,020.62	−£393.43	This scenario is in line with the SPC guidance for alprostadil: some patients may require more than three visits for titration purposes. However, the SPC for aviptadil/phentolamine also recommends regular monitoring (e.g. three-monthly) in the initial stages of self-injection therapy. This scenario is therefore relatively implausible.
Priapism rate with alprostadil increased from 0.40% to 1%	£627.20	£941.19	−£313.99	A rate of 1% is reflective of the findings from Dinsmore *et al*, 1999[10]. This scenario therefore offers a plausible alternative to the base case.
Time horizon increased to five years	£2,422.21	£2,956.81	−£534.61	It is plausible that patients will continue treatment for longer than one year. It is also plausible that patients continue treatment for longer than five years.
Patients who experience palpitation, flushing and testicular pain are seen by a consultant	£647.00	£915.16	-£268.16	While this scenario allows for exploration of the potential impact of the bias of omitting costs for these events, it is uncertain whether these adverse events would require a consultant appointment, and thus whether this scenario is more plausible than the base case.
Total of three consultant appointments for aviptadil/phentolamine in the first year (same as alprostadil)	£827.20	£911.12	−£83.93	The SPC for aviptadil/phentolamine recommends regular monitoring (e.g. three-monthly) in the initial stages of self-injection therapy. This AWTTC suggested scenario therefore offers a plausible alternative to the base case.

AWTTC: All Wales Therapeutics and Toxicology Centre; SPC: summary of product characteristics.

4.1.3 AWTTC critique

The reliability of the CMA presented is dependent on the extent to which aviptadil/phentolamine is considered to be therapeutically equivalent to alprostadil. The CMA approach has been justified by the company on the grounds of similar efficacy between the treatments. However, a CMA approach should be based on equivalence in terms of efficacy and evidence of close comparability of other effects such as quality of life and adverse events. The submission does not provide sufficient data to unequivocally demonstrate equivalence in efficacy. Study VP 007 was conducted in patients who were naive to PDE5 inhibitors. Patients in the study received three different doses of aviptadil/phentolamine and four different doses of alprostadil, as well as two different formulations (ampoule and auto-injector) of aviptadil/phentolamine. The results were not presented according to dose or formulation, thereby making it difficult to assess the relative effectiveness and adverse events associated with the two treatments. Furthermore, as discussed in Section 3.1, the dose-finding phase of the study showed alprostadil to be significantly more effective than aviptadil/phentolamine[9]. The company also acknowledges that there are differences in the adverse event profiles of aviptadil/phentolamine and alprostadil, especially with regards to pain, priapism, and penile fibrosis. Collectively, these limitations undermine the case for using CMA to assess cost effectiveness.

Strengths of the economic analysis are as follows:

- The submission gives a transparent account of methods, data sources and analyses undertaken.
- The company has sought clinical expert opinion to strengthen assumptions where there is lack of higher level evidence.
- A variety of sensitivity and scenario analyses have been conducted.

Limitations of the economic analysis are as follows:

- The company has assumed patients treated with aviptadil/phentolamine require one consultant visit. However, the SPC documentation recommends regular (e.g. three-monthly) visits for monitoring in the initial stages of self-injection therapy. Given that the cost savings in the model are predominantly generated by differences in the number of consultant visits between the treatments, this assumption has the potential to bias the results in favour of aviptadil/phentolamine. To explore the impact of this potential bias, AWTTC have conducted additional analyses based on patients treated with aviptadil/phentolamine requiring extra consultant visits (see last scenario in Table 2). If it is assumed that both treatments require three visits, aviptadil/phentolamine remains cost saving.
- The findings of study VP 007 suggest that despite an overall dose-response trend, some patients who responded to the higher dose of aviptadil/phentolamine (25 micrograms/2 mg) also responded to lower doses of alprostadil. These findings suggest it may have been more appropriate to use a wider range of doses for the comparator in the base case. However, scenario analyses have been conducted to explore the impact on the cost comparison of different dosing ratios, and these suggest that the use of aviptadil/phentolamine remains cost-saving when compared against a combination of higher and lower doses of alprostadil. Nevertheless, there is no exploration or discussion of whether or not adverse events are dose related, or how this could influence the results of the analyses.
- Time horizon is limited to one year in the base case and five years in the scenario analysis. This fails to capture the costs of continued administration.
- The company suggest that all moderate and severe adverse events are included in the model. However, only two specific adverse events (priapism and penile fibrosis) are included. Based on company-sought expert opinion, it is assumed that these two adverse events are not a risk for patients receiving aviptadil/phentolamine. However, the SPC lists both of these adverse events as

possible (albeit rare) risks of treatment with aviptadil/phentolamine[2]. This has the potential to bias the base case analysis in favour of aviptadil/phentolamine. The impact of this potential bias has not been explored by the company.

- The three other adverse events that have been omitted from the base case model, namely palpitation, flushing and testicular pain, are estimated as occurring at a higher rate in patients treated with aviptadil/phentolamine. The omission of these therefore biases the cost comparisons in favour of aviptadil/phentolamine. However, following discussions with AWTTC the company have provided a scenario analysis to address this (see Table 2).

4.2 Review of published evidence on cost-effectiveness

A literature review conducted by AWTTC did not identify any published studies evaluating the cost-effectiveness of aviptadil/phentolamine.

5.0 SUMMARY OF EVIDENCE ON BUDGET IMPACT

5.1 Budget impact evidence

5.1.1 Context and methods

The company has used IMS sales data to guide budget impact estimates. IMS sales data show that the average number of alprostadil units sold in the UK between 2013 and 2014 was 282,506. The company uses Office of National Statistics population figures to apportion 4.76% of these sales to Wales[23]. The resultant annual sales figure of 13,447 units is further inflated using population growth statistics[19] to forecast the sale of 13,602 units in 2017. Applying the assumption that patients will inject once weekly, the company estimate that 262 patients will be eligible for treatment in 2017. An assumed market share of 10% in year one, increasing to 30% in years three to five, is further applied to estimate the number of patients likely to be prescribed aviptadil/phentolamine in Wales. No sensitivity analyses have been performed to test the robustness of the findings of the budget impact model to changes in input parameter values.

5.1.2 Results

The budget impact analyses are presented in Table 3. Under the base case assumptions, the drug acquisition costs for alprostadil are £14.70 higher per patient than aviptadil/phentolamine in the first year of administration, as a result of titration cost differences. In subsequent years there are no differences in acquisitions costs. This results in acquisition cost savings of approximately £385 in year one, followed by savings ranging from approximately £197 to £206 in subsequent years. The introduction of aviptadil/phentolamine is also reported to impact on NHS resource use: savings accrue as a result of fewer consultant visits for titration/monitoring and lower incidence of priapism and penile fibrosis associated with aviptadil/phentolamine. The value of these resource savings are estimated at £7,054 in year one, and between £5,407 and £8,318 in years two to five.

Table 3. Estimated five year budget impact associated with the use of aviptadil/phentolamine mesilate for the treatment of erectile dysfunction

	Year 1 2017	Year 2 2018	Year 3 2019	Year 4 2020	Year 5 2021
Number of eligible patients	262	263	264	265	266
Uptake of new medicine (%)	10	15	20	25	30
Number of patients treated with aviptadil/phentolamine	26	39	53	66	80
Net medication costs (£)	−£385.14	−£196.70	−£199.42	-£202.33	−£205.67
Cumulative net cost (£)	**−£385.14**	**−£581.84**	**−£781.26**	**−£983.59**	**−£1,189.26**

5.1.3 AWTTC critique

- The submission gives a detailed, transparent account of the methods and data sources used to estimate budget impact.
- AWTTC have independently analysed prescribing data in Wales[24], and if the once-weekly administration assumption is applied, these suggest that patient numbers may be higher than those reported by the company. The potential for budget impact savings may therefore be higher than reported. Additionally, Welsh prescribing data reveals that different doses of alprostadil are used in Wales. Injections packs of alprostadil 40 mcg are associated with the second largest sales quantity when all doses are compared. Given that the unit cost associated with this 40 mcg is higher than the comparator dose (see Table 4), there is potential for higher savings than estimated in the base case. Consequently, there is uncertainty surrounding the projected acquisition cost savings.
- The estimates for uptake are based on sales data from other European countries (Denmark and Sweden) and clinical expert opinion. Whilst efforts have been made to forecast market share in an informed way, these estimates remain subject to uncertainty, as in all budget impact analyses.
- The SPCs for both drugs recommend that patients are regularly monitored when initiated on treatment. The model assumes this is only necessary for alprostadil. Consequently, the resource savings attributed to differences in consultation requirements are subject to uncertainty. If it is assumed that the consultation requirements for both medicines is three visits, this decreases the resource use savings to £1,814 in year one.
- Discontinuation due to adverse events it not explicitly addressed in the model. Also, risk of adverse events is implicitly stable over time. Together with the fact that not all moderate to severe adverse events have been costed in the model, this creates some uncertainty around the resource savings attributed to adverse event differences. If the cost of treating palpitation, flushing and testicular pain, are included in the model this reduces resource use savings in year one to £6,640.
- Collectively, there is uncertainty surrounding the estimated financial and resource savings produced by the budget impact model. If the model is adjusted to include three consultation visits for both medicines and costs for the three adverse events listed above, this reduces the 5-year cumulative savings from £34,482 to £14,133.

5.2 Comparative unit costs

Table 4 provides an overview of the unit costs associated with intracavernous treatments for erectile dysfunction. The annual costs listed have been calculated using the assumption of 50 injections per year. However, it should be noted that this does not represent maximum dosing for these treatments, merely a comparative costing.

Table 4. Examples of medicine acquisition costs for intracavernous injections for the treatment of erectile dysfunction

Regimens	Example doses	Approximate costs per 50 injections
Aviptadil/phentolamine mesilate (Invicorp®)	25 micrograms/2 mg	£475
Alprostadil (Caverject®) dual chamber	10 micrograms	£367.50
Alprostadil (Caverject®) dual chamber	20 micrograms	£475
Alprostadil (Caverject®) vials	5 micrograms	£386.50†
Alprostadil (Caverject®) vials	10 micrograms	£462
Alprostadil (Caverject®) vials	20 micrograms	£597
Alprostadil (Caverject®) vials	40 micrograms	£1079

Not all regimens may be licensed for use in this patient population. See relevant summaries of product characteristics[2,14,15,25-28] for full licensed indications and dosing details.
Costs are based on MIMS[29] and BNF[30†] list prices as of February 2017.
Costs of administration are not included.
This table does not imply therapeutic equivalence of drugs or the stated doses.

6.0 ADDITIONAL INFORMATION

6.1 Prescribing and supply

AWTTC is of the opinion that, if recommended, aviptadil/phentolamine mesilate (Invicorp®) for the indication under consideration may be appropriate for use within NHS Wales prescribed under specialist recommendation.

The company does not anticipate that aviptadil/phentolamine (Invicorp®) will be supplied by a home healthcare provider.

6.2 Ongoing studies

The company submission states that there are no ongoing studies from which additional evidence is likely to be available within the next 6–12 months.

6.3 AWMSG review

This assessment report will be considered for review three years from the date of the Final Appraisal Recommendation.

6.4 Evidence search

Date of evidence search: 23 February 2017.
Date range of evidence search: No date limits were applied to database searches.

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