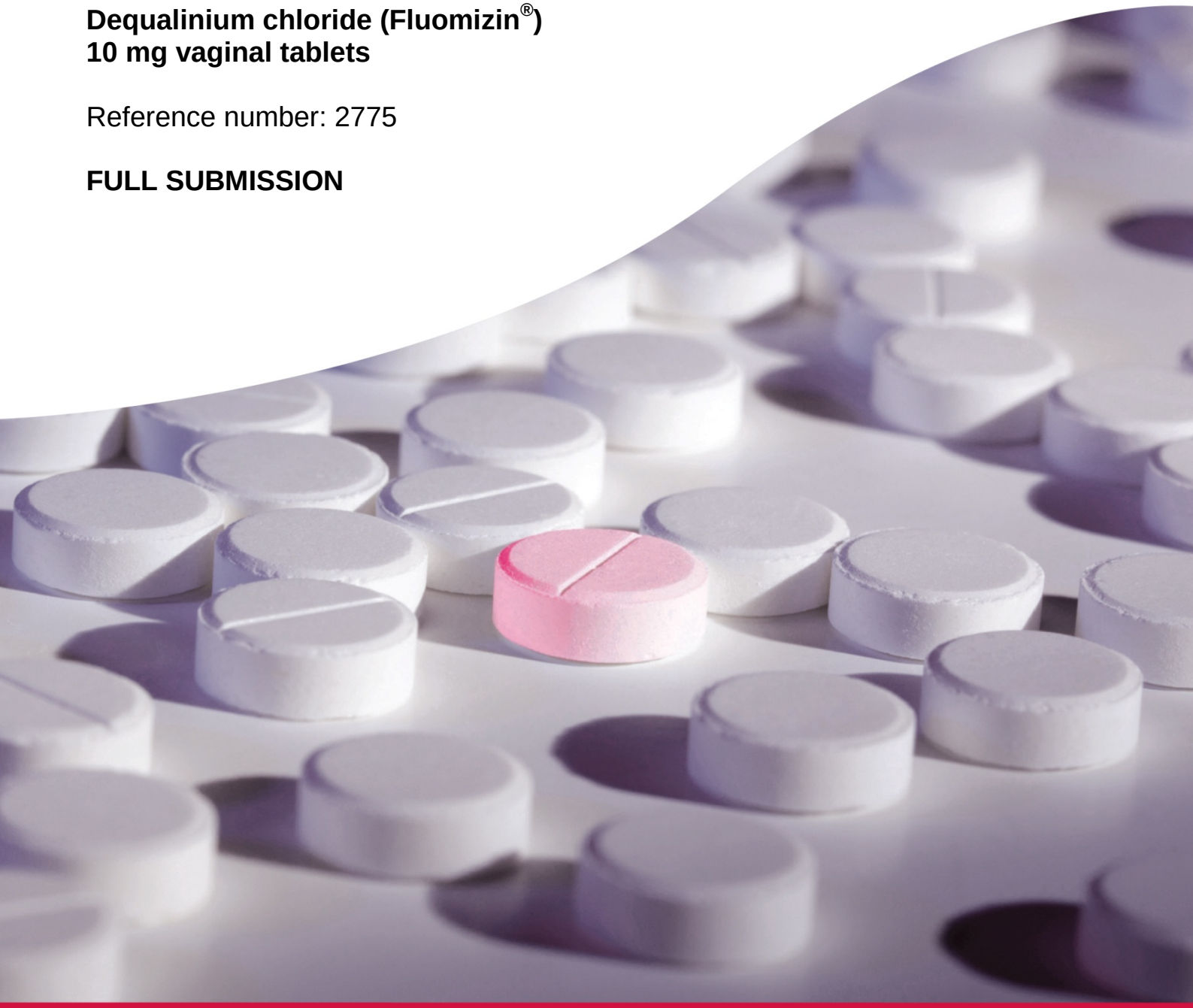
All Wales Therapeutics and Toxicology Centre
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

AWMSG SECRETARIAT ASSESSMENT REPORT

Dequalinium chloride (Fluomizin®) 10 mg vaginal tablets

Reference number: 2775

FULL SUBMISSION



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AWMSG Secretariat Assessment Report
Dequalinium chloride (Fluomizin®) 10 mg vaginal tablets

This assessment report is based on evidence submitted by Kora Healthcare[1].

1.0 PRODUCT DETAILS

Licensed indication under consideration	Dequalinium chloride (Fluomizin®) for the treatment of bacterial vaginosis[2].
Dosing	The recommended dose is one vaginal tablet daily for six days[2]. Refer to the Summary of Product Characteristics (SPC) for further information regarding dosing[2].
Marketing authorisation date	30 June 2015[2]
UK launch date	April 2016[1]

2.0 DECISION CONTEXT

2.1 Background

Bacterial vaginosis is the most common cause of abnormal vaginal discharge in women of child-bearing age[3]. It is characterised by a change in the bacterial populations in the vagina: a decrease in numbers of *Lactobacillus* bacteria is accompanied by an overgrowth of predominantly anaerobic bacteria such as *Gardnerella, Prevotella and Mycoplasma* species[4]. Clinical features include malodorous vaginal discharge, which is not usually associated with signs of inflammation, soreness or irritation[3], although symptoms are only present in about half of women with bacterial vaginosis[4]. Although not regarded as a sexually transmitted disease, the prevalence of bacterial vaginosis is generally higher among sexually active women than in non-sexually active women[3]. In pregnancy, bacterial vaginosis is associated with late miscarriage, pre-term labour, pre-term birth, pre-term premature rupture of membranes, low birth weight and postpartum endometritis[4].

Clinical guidelines recommend 400 mg twice-daily oral metronidazole for 5–7 days, 0.75% metronidazole vaginal gel for 5 days, or 2% clindamycin vaginal cream for 7 days as treatment options for bacterial vaginosis[3,5]. Oral metronidazole is the treatment of choice; metronidazole vaginal gel or clindamycin vaginal cream are alternative options if topical treatment is preferred or if oral metronidazole is not tolerated[4]. All of these treatments have reported cure rates of 70–80%[3], but recurrence is common[6].

Dequalinium chloride (Fluomizin®) is a quaternary ammonium derivative with broad-spectrum anti-infective and antiseptic properties[2]. It acts on bacterial cells by increasing cell wall permeability and causing a loss of bacterial enzyme activity followed by cell death[2]. Dequalinium chloride vaginal tablets act locally within the vagina and show rapid bactericidal activity, with effects within 30–60 minutes[2].

The company has requested that AWMSG consider dequalinium chloride vaginal tablets as an alternative to clindamycin vaginal cream for the treatment of bacterial vaginosis after the initial treatment was ineffective or not tolerated[1].

2.2 Comparators

The comparator included in the company's submission was 2% clindamycin vaginal cream[1].

2.3 Guidance

- All Wales Medicines Strategy Group (2015). Primary care antimicrobial guidelines[5]
- Royal College of General Practitioners, British Association for Sexual Health and HIV (2013). Sexually transmitted infections in primary care[7]
- British Association for Sexual Health and HIV (2012). UK national guideline for the management of bacterial vaginosis 2012[3]

3.0 SUMMARY OF EVIDENCE ON CLINICAL EFFECTIVENESS

The company's submission includes efficacy and safety data from one phase III non-inferiority study comparing the efficacy of dequalinium chloride 10 mg vaginal tablets with that of clindamycin 2% vaginal cream in treating bacterial vaginosis[1].

3.1 Phase III comparative study (NCT101125410)

This randomised study was conducted in 15 centres across five European countries[8]. It enrolled 321 premenopausal women aged 18–55 years (one was aged 16 years) with bacterial vaginosis diagnosed by the presence of all four Amsel criteria[9]: a grey, homogeneous, malodorous discharge; pH > 4.5; positive potassium hydroxide test for amines; and clue cells constituting ≥ 20% of epithelial cells on a wet mount. Exclusion criteria included pregnancy. Patients were randomised to treatment with either a dequalinium chloride 10 mg vaginal tablet once daily for 6 days (n = 164) or clindamycin 2% vaginal cream once daily for 7 days (n = 157). The incidence of previous episodes of bacterial vaginosis was comparable between treatment groups (69.3% in the dequalinium chloride group and 71.7% in the clindamycin group), but details of previous treatments were not recorded[8].

Safety, tolerability and efficacy were evaluated at follow-up visits 7 days (C1) and 25 days (C2) after the end of treatment. Study investigators who evaluated efficacy were blinded to the study medication[8]. The primary efficacy outcome was clinical cure at the first follow-up visit, which was defined as absence of clue cells and a negative result for at least two other Amsel criteria[8]. Secondary efficacy outcomes included clinical cure at second follow-up visit, clinical improvement at first and second follow-up visits (two or more Amsel criteria negative) and rate of treatment failures at second follow-up visit[8].

Clinical cure rates are shown in Table 1. In the intent-to-treat populations, similar cure rates were achieved at both follow-up visits for women treated with dequalinium chloride and those treated with clindamycin; the two-sided 95% confidence interval for the difference between treatments was within the pre-specified margin of ± 15%, demonstrating non-inferiority of dequalinium chloride to clindamycin. Similar results were seen in the per-protocol-set analyses[8].

Table 1: Clinical cure rates for dequalinium chloride and clindamycin in the treatment of bacterial vaginosis[8]

	Total (n)	Missing (n)	Cured (n)	Cure rate (%)	$CI_{95\%diff}$ (%)
7-day follow-up visit (C1)					
Per-protocol-set*					
Dequalinium chloride	135	n/a	110	81.5	–7 to 13
Clindamycin	116	n/a	91	78.4	
Intention-to-treat population					
Dequalinium chloride	163	5	126	79.7	–8 to 10
Clindamycin	152	11	111	78.7	
25-day follow-up visit (C2)					
Per-protocol-set*					
Dequalinium chloride	135	3	105	79.5	–8 to 12
Clindamycin	116	n/a	90	77.6	
Intention-to-treat population					
Dequalinium chloride	163	8	116	74.8	–10 to 10
Clindamycin	152	9	107	74.8	

*A total of 64 women were excluded from the per-protocol-set population because of major protocol deviations: 28 in the dequalinium chloride group and 36 in the clindamycin group. The most common protocol deviations were: time window violations, prior termination, investigator acting as 'treating' and 'evaluating' physician for the same woman, and violations of exclusion and inclusion criteria. There were no apparent differences between the groups.

CI: confidence interval; $CI_{95\%diff}$: two-sided 95% confidence interval for the difference in clinical cure rates; n/a: not applicable

For secondary endpoints, there were no significant differences in Amsel criteria between the treatment groups except for vaginal pH, which was significantly more often below 4.5 at the first follow-up visit in women treated with dequalinium chloride than in those treated with clindamycin ($p = 0.02$). There were no differences in the global efficacy assessments by investigators and patients[8].

3.2 Comparative safety

In the non-inferiority phase III study in 321 patients, no serious adverse events were reported[8]. At first and second follow-up visits, more than 90% of the women treated and the study investigators judged the overall tolerability of treatment as very good or good. There were no statistically significant differences between the numbers of adverse events reported in the dequalinium chloride (n = 134; 40.5%) and clindamycin (n = 163; 47.7%) treatment groups[8]. The two most frequently reported adverse drug reactions were vaginal discharge, occurring in 9.2% of dequalinium chloride-treated women and 4.6% of clindamycin-treated women; and vulvovaginal pruritus, occurring in 4.9% of dequalinium chloride-treated women and 8.5% of clindamycin-treated women[8].

3.3 AWTTC critique

- Dequalinium chloride 10 mg vaginal tablets are licensed for treating bacterial vaginosis. The company has requested consideration for their use as an alternative option to clindamycin 2% vaginal cream to treat bacterial vaginosis in women for whom initial treatment is ineffective or not tolerated. The company justified positioning dequalinium chloride vaginal tablets as an alternative option to clindamycin vaginal cream after oral metronidazole or metronidazole vaginal gel based on current UK and Welsh guidelines and a survey of sexual healthcare professionals at 6 hospitals in Wales. Clinical expert opinion sought by AWTTC suggests that oral metronidazole is the usual initial treatment of choice, with metronidazole vaginal gel or clindamycin vaginal cream as alternative options.

- The population in the pivotal study represents the full licensed indication for dequalinium chloride vaginal tablets and was not restricted to the subpopulation of patients described by the company.
- The company assumed that the choice of treatment would be based purely on economic factors, with no differences between the groups; however, decisions in practice may depend on other factors such as patient preference, suitability and tolerance. Including oral metronidazole and metronidazole vaginal gel as comparators may have been more representative of practice and reflective of the choice of treatments set out in guidelines.
- There were no serious adverse events reported in the study. Fewer adverse events occurred in the dequalinium chloride group than in the clindamycin group, but there was no statistically significant difference between the two treatment groups[8]. Common undesirable effects listed in the SPC for dequalinium chloride vaginal tablets include vulvovaginal pruritus and vulvovaginal burning sensation[2].
- Dequalinium chloride is a broad-spectrum antiseptic and not an antibiotic, unlike clindamycin. Its use as an alternative to clindamycin would provide an alternative treatment option and may help to reduce broad-spectrum antibiotic use in Wales, in line with antimicrobial stewardship.
- The systemic absorption of dequalinium chloride vaginal tablets is negligible[2], whereas that of clindamycin vaginal cream is approximately 4%[10]. Dequalinium chloride vaginal tablets do not impair the functionality of latex condoms[2]; clindamycin vaginal cream contains oil-based components that may make condoms less effective as a form of contraception during treatment[10].
- Dequalinium chloride vaginal tablets would provide an alternative treatment option for women with a history of inflammatory bowel disease or antibiotic-associated colitis, in whom clindamycin is contraindicated[10]. Clindamycin vaginal cream is not recommended for use in women who have sensitivity to lincomycin[10].

4.0 SUMMARY OF THE EVIDENCE ON COST-EFFECTIVENESS

4.1 Cost-effectiveness evidence

4.1.1 Context

The company's submission describes a cost minimisation analysis (CMA) of dequalinium chloride vaginal tablets in comparison with clindamycin vaginal cream as second-line treatment for bacterial vaginosis after the initial treatment with metronidazole was ineffective or not tolerated. This use would be for a sub-group of the full population covered by the licensed indication[1].

Dequalinium chloride vaginal tablets have been positioned as an alternative treatment to clindamycin vaginal cream based on:

- feedback from questionnaires sent to healthcare professionals in NHS Wales
- data from a randomised clinical trial that showed equivalent efficacy and safety of dequalinium chloride compared with clindamycin vaginal cream[8]
- the fact that both medications act locally rather than systemically.

It has been assumed that the efficacy and safety profile of dequalinium chloride vaginal tablets and clindamycin vaginal cream are equivalent. This assumption was based on a clinical study comparing dequalinium chloride vaginal tablets and clindamycin vaginal cream in an unrestricted population diagnosed with bacterial vaginosis[8]. The company reports that the overall findings of this study apply equally to the sub-population considered in this submission, with the distinction drawn purely for economic reasons.

Medicine acquisition costs were sourced from the Dictionary of Medicines and Devices[11-13]. It was assumed that one pack of dequalinium chloride or clindamycin

would be used per treatment in accordance with the Summary of Product Characteristics (SPC)[2,10]. The post-treatment complication vulvovaginal candidiasis (VVC) was assumed to be treated with a fluconazole capsule and clotrimazole cream in accordance with guidance from the British Association for Sexual Health and HIV (BASHH)[3]. It was assumed that medicines would be prescribed by a GP. The cost of a GP visit was sourced from the Personal Social Services Research Unit assuming an average consultation time of 11.7 minutes per patient[14].

Total costs were estimated over a one-year time horizon. A shorter time horizon of 25 days (reflecting the clinical study) was explored in sensitivity analyses. No discounting was performed in any scenario because of the short time horizons considered.

A series of eight sensitivity analyses were conducted, examining variations in clearance levels, rates of VVC, the time horizon and treatment switching rules following non-clearance and recurrence.

4.1.2 Results

The results of the base case analysis are presented in Table 2. Dequalinium chloride vaginal tablets are reported to have a cost saving of [commercial in confidence figure removed] per treatment course in comparison with clindamycin cream. The efficacy of the two medicines was assumed to be equivalent.

Table 2: Results of the base case analysis

	Dequalinium chloride vaginal tablets	Clindamycin cream	Difference
Total costs	¶¶	¶¶	¶¶

The results of the sensitivity analyses are presented in Table 3. Dequalinium chloride was reported to be cost saving in seven of the eight scenarios modelled. Clindamycin was favoured in sensitivity analysis 5 in which the lower bound of the clearance rate for dequalinium chloride and upper bound of the clearance rate for clindamycin were applied.

Table 3: Results of scenario analyses

Sensitivity analysis	Dequalinium chloride vaginal tablets	Clindamycin cream	Difference	Plausibility
Sensitivity analysis 1 24 day time horizon based on duration of study NCT101125410[8].	¶¶	¶¶	¶¶	The modelled time horizon should reflect the period over which outcomes could be expected to differ. As such, the longer base case time horizon may be more appropriate.
Sensitivity analysis 2 Lowest reported clearance levels	¶¶	¶¶	¶¶	Plausible scenario based on the lower and upper effectiveness boundaries reported in study NCT101125410[8].
Sensitivity analysis 3 Highest reported clearance levels	¶¶	¶¶	¶¶	
Sensitivity analysis 4 Equal probabilities of vulvovaginal candidiasis (VVC)	¶¶	¶¶	¶¶	The difference in VVC rates reported in study NCT101125410 were not statistically significant[8]. Therefore a plausible

Sensitivity analysis	Dequalinium chloride vaginal tablets	Clindamycin cream	Difference	Plausibility
				scenario.
Sensitivity analysis 5 Lowest clearance level for dequalinium chloride and highest clearance for clindamycin	¶¶	¶¶	¶¶	Plausible scenario based on favourable and unfavourable combinations of effectiveness boundaries reported in study NCT101125410[8].
Sensitivity analysis 6 Highest clearance level for dequalinium chloride and lowest clearance for clindamycin	¶¶	¶¶	¶¶	
Sensitivity analysis 7 Same pathway as sensitivity analysis 1, but if non-clearance occurs the patient should repeat previous treatment	¶¶	¶¶	¶¶	There is no definitive guidance on treatment following recurrence or non-clearance. The dequalinium chloride SPC states that there are no efficacy and safety data available on the re-treatment of patients who did not respond to or relapsed after initial therapy[2]. Therefore, re-challenging with initial treatment or switching treatment both appear to be decisions that could reasonably be taken in clinical practice.
Sensitivity analysis 8 Same pathway as sensitivity analysis 1, but if recurrence occurs the patient should switch to an alternative treatment as the treatment is deemed unsuccessful	¶¶	¶¶	¶¶	

4.1.3 AWTTC critique

The reliability of the CMA presented by the company depends on the extent to which dequalinium chloride is considered to be therapeutically equivalent to the relevant comparators. The company's analysis is based on the clinical study showing the non-inferiority of dequalinium chloride vaginal tablets to clindamycin cream[8]. However, non-inferiority does not infer equivalence. Furthermore, the population covered in the study does not match the restricted population of patients whose initial treatment was ineffective or not tolerated. Effectiveness in this sub-group alone has not been demonstrated.

The uncertainty around the assumption of therapeutic equivalence has been partly explored in sensitivity analyses of variations in clearance rates. However, the CMA approach that has been adopted does not allow for this uncertainty to be fully explored because it is restricted to costs.

Clindamycin cream was the sole comparator considered in the analysis. This is only appropriate if the population is restricted to patients in whom initial treatment with metronidazole is ineffective or not tolerated. If it is possible to treat patients with metronidazole then the analysis should also cover these comparators. This point is particularly salient since it is possible to use metronidazole in the treatment of recurrent disease[4]. The definition of the point at which metronidazole is deemed to be ineffective is therefore key. The company have stated that they would deem metronidazole to be ineffective when the patient returns with symptoms of bacterial vaginosis following two consecutive rounds of treatment with oral metronidazole. Clinical expert opinion sought by AWTTC suggests that this is reflective of practice. However, there remains

some uncertainty with this definition because there is no consensus on the optimal treatment of recurrence.

Strengths of the economic evidence include:

- The company has adopted a pragmatic approach in its use of CMA.
- The analysis combines data from numerous sources and demonstrates a clear understanding of the disease area.
- A range of sensitivity analyses have been conducted, addressing some of the areas of uncertainty in the model.
- The analysis is clearly reported and well referenced.

Limitations of the economic evidence include:

- The therapeutic equivalence of dequalinium chloride vaginal tablets and clindamycin cream has not been strictly demonstrated because the clinical study demonstrating non-inferiority does not match the restricted population.
- The CMA framework assumes equivalence in all domains of health outcomes which precludes exploration of the differences that may exist in efficacy, safety and health-related quality of life.
- The analysis is restricted to one recurrence after clindamycin cream or dequalinium chloride vaginal tablets. It is plausible that there could be multiple recurrences over the one-year time horizon covered in the analysis. However, it is recognised that there is a lack of clinical evidence covering this aspect and the company reports that the data used in the analysis are from the best evidence currently available. Furthermore, assuming that the rate and treatment of subsequent recurrences would be the same in each treatment arm, it is possible that the costs associated with subsequent recurrences may cancel out.
- Since VVC is managed using a treatment that is widely available over the counter, it is perhaps unreasonable to assume that a GP visit and prescription would be needed in all cases of VVC.
- Economic analyses typically use effectiveness data from intention-to-treat (ITT) populations rather than the per-protocol-set (PPS) population used in this analysis. However, because non-inferiority was demonstrated in both populations, the impact of this is likely to be minimal.

4.2 Review of published evidence on cost-effectiveness

The standard literature searches conducted by the AWTTC did not identify any relevant economic evidence.

5.0 SUMMARY OF EVIDENCE ON BUDGET IMPACT

5.1 Budget impact evidence

5.1.1 Context and methods

The company reported that there are no data on the prevalence of bacterial vaginosis in Wales. The prevalence was therefore estimated using data from two peer-reviewed studies. Population data from a UK study in pregnant women, reporting a 12% prevalence[15] and a US national health survey reporting a 23% prevalence[16] were combined to give an average bacterial vaginosis prevalence of 21%. Because bacterial vaginosis is an acute infection, this figure reflects the likely prevalence of bacterial vaginosis at any point in time. Furthermore, the figure includes both first and recurrent cases of bacterial vaginosis, because the studies made no distinction between the two.

In both studies, only prevalence data for Caucasian subjects were used in order to better reflect the population of Wales, where 95.6% of the population is Caucasian[17]. The company estimated that the total number of Caucasian women aged 18–55 in Wales was 707,000, based on data from the 2011 census[17]. Multiplying this figure by

the estimated prevalence of 21% gave an estimate of 148,000 women with bacterial vaginosis.

Based on an estimate from BASHH guidelines[3], it was assumed that 50% of the 148,000 women with bacterial vaginosis (74,000) would be asymptomatic and would therefore not seek medical intervention. The remaining 74,000 who are symptomatic were assumed to seek treatment for bacterial vaginosis from their GP or genitourinary medicine clinic, where they were assumed to receive metronidazole as first-line treatment.

Based on data from two clinical studies, it was estimated that 75% of women (55,000) would be cleared of bacterial vaginosis after treatment with metronidazole[18,19]. The 25% of women who were not cleared (18,000) were assumed to receive a repeated dose of metronidazole. This assumption was based on 2015 PCA data for the sales volume of clindamycin cream[20], which the company viewed as showing that the initial dose of treatment would be repeated following non-clearance or recurrence.

Of the 55,000 women estimated to be cleared of bacterial vaginosis after initial treatment with metronidazole, it was estimated that 23% (13,000) would experience a recurrence after one month[6]. As above, these women were assumed to receive a repeated dose of metronidazole.

Women not achieving clearance or experiencing a recurrence after the second treatment with metronidazole were assumed to be available for treatment with dequalinium chloride. Based on this, the company estimated that 7,800 women were available for second-line treatment with dequalinium chloride. Over the five-year period covered in the costing, the company assumed that the total number of women available for second-line treatment would remain constant at 7,800 because this figure was based on the prevalence of bacterial vaginosis at any point in time.

The company estimated that the uptake rate of dequalinium chloride [commercial in confidence text removed]. [Commercial in confidence text removed] Also, unlike clindamycin, dequalinium chloride is not an antibiotic and it is therefore expected to benefit from the strategy to reduce the use of antibiotics in Wales, as outlined in antimicrobial stewardship guidelines[21].

The company estimated the net cost of introducing dequalinium chloride as the difference in the medication cost of dequalinium chloride vaginal tablets and clindamycin cream (£3.91). No additional costs or savings associated with the use of the medicine under consideration and its comparator were anticipated. The patient will be treated using the same level of medical intervention and testing as is the current practice. The saving to the NHS Wales is solely on a pack-for-pack cost price.

A series of six sensitivity analyses were conducted, in which parameters relating to the number of eligible patients and the uptake rate were varied. Parameters relating to the net cost calculation were unchanged in these analyses.

5.1.2 Results

[Commercial in confidence text removed]

Table 4: Company-reported costs associated with use of dequalinium chloride for the second-line treatment of bacterial vaginosis

	Year 1	Year 2	Year 3	Year 4	Year 5
Number of eligible patients (indication covered in this submission)	¶¶	¶¶	¶¶	¶¶	¶¶
Uptake (%)	¶¶	¶¶	¶¶	¶¶	¶¶
Treated patients	¶¶	¶¶	¶¶	¶¶	¶¶
Net costs					
Medication costs	¶¶	¶¶	¶¶	¶¶	¶¶
Savings from displaced medicine	¶¶	¶¶	¶¶	¶¶	¶¶
Overall net cost	¶¶	¶¶	¶¶	¶¶	¶¶

[Commercial in confidence text removed]. Sensitivity analysis 7 was particularly noteworthy because it expanded the number of eligible patients to include an estimate of those women who would be deemed intolerant to first-line treatment. [Commercial in confidence text removed].

5.1.3 AWTTC critique

- The company reported a lack of relevant epidemiological data. The company has therefore been pragmatic and has estimated the number of eligible patients in Wales by combined existing data appropriately.
- As in all budget impact analyses, the estimation of uptake rates is somewhat speculative and subject to uncertainty. However, the company has provided a clear justification for its estimations and has varied the uptake rates in sensitivity analyses.
- The estimated number of eligible patients does not include the number of women who have a recurrence after initial treatment with metronidazole who are then unsuccessfully re-treated with metronidazole. At present, the analysis only includes women who are not cleared after the initial treatment who are then not cleared or experience a recurrence after repeat treatment. The eligible population could therefore be up to 5,400 higher than that reported.
- Dequalinium chloride vaginal tablets have been positioned as an alternative treatment to clindamycin cream after the initial treatment was ineffective or not tolerated. However, the base case budget impact analysis focuses only on women for whom the initial treatment was ineffective with the number of women for whom initial treatment is not tolerated included only in sensitivity analyses.
- In sensitivity analysis 7, the number of women for whom initial treatment is not tolerated may be underestimated. According to the company, the incidence of side effects reported in studies using oral metronidazole varies from 10% to 50%. The lower end of this spectrum (10%) is used in the population estimate for the sensitivity analysis.

5.2 Comparative unit costs

Table 5 provides example comparative acquisition costs for dequalinium chloride vaginal tablets and clindamycin cream based on current list prices in the first year of treatment.

Table 5: Examples of medicine acquisition costs for dequalinium chloride and comparators in the second-line treatment of bacterial vaginosis

Regimens	Example doses	Approximate treatment cost per patient
Dequalinium chloride 10 mg vaginal tablets, pack of 6	One 10 mg vaginal tablet once a day for 6 days	£6.95
Clindamycin 2% vaginal cream 40 g	One applicator full intravaginally at bedtime for 7 consecutive days	£10.86
Metronidazole 400 mg tablets	One 400 mg tablet twice daily for 5–7 days	£0.63 to £0.75
Metronidazole 0.75% vaginal gel 40 g	One applicator full intravaginally at bedtime for 5 consecutive days	£4.31
See relevant Summaries of Product Characteristics for full licensed indications and dosing details[2,10] Dequalinium chloride vaginal tablets cost based on MIMS list prices as of July 2016[22] Clindamycin cream, metronidazole 0.75% vaginal gel and metronidazole 400 mg tablets cost based on NHS Drug Tariff as of July 2016[23] Costs of administration are not included. This table does not imply therapeutic equivalence of medicines or the stated doses.		

6.0 ADDITIONAL INFORMATION

6.1 Prescribing and supply

AWTTC is of the opinion that, if recommended, dequalinium chloride (Fluomizin®) may be appropriate for prescribing by all prescribers within NHS Wales for the indication under consideration.

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: 13 July 2016
Date range of evidence search: No date limits were applied to database searches.

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