

CADTH COMMON DRUG REVIEW

Pharmacoeconomic Review Report

FLUTICASONE PROPIONATE (AERMONY RESPICLICK)

(Teva Canada Innovation)

Indication: For the maintenance treatment of steroid-responsive bronchial asthma as prophylactic therapy in patients 12 years of age and older

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Abbreviations

CDR	CADTH Common Drug Review
ICS	inhaled corticosteroid
Fp	fluticasone propionate
HFA	hydrofluoroalkane
MDPI	multidose dry powder inhaler

Drug	Fluticasone propionate (Aermony RespiClick)
Indication	For the maintenance treatment of steroid responsive bronchial asthma as prophylactic therapy in patients 12 years of age and older
Reimbursement Request	As per indication
Dosage Form(s)	Dry powder for inhalation, available as 55 mcg, 113 mcg, and 232 mcg per actuation
NOC Date	August 22, 2017
Manufacturer	Teva Canada Innovation

Executive Summary

Background

Fluticasone propionate (Fp) is an inhaled corticosteroid (ICS), available as a multidose dry powder inhaler (MDPI) (Fp MDPI; Aermony RespiClick). It is indicated for the maintenance treatment of steroid-responsive bronchial asthma in patients 12 years of age or older.¹ The submitted price for a 60-dose pack of Fp MDPI is \$16.96 for 55 mcg, \$30.96 for 113 mcg, and \$48.15 for 232 mcg. The dose of Fp MDPI depends on the severity of the disease. At the recommended dose, administration of one inhalation twice daily, Fp MDPI costs between \$206 and \$586 per patient per year.²

Fp is available as an individual treatment in several different inhaler formats, including Fp Diskus (Flovent Diskus) and Fp hydrofluoroalkane (HFA) (Flovent HFA),³ though none of these were reviewed by CDEC.

Summary of the Economic Analysis Submitted by the Manufacturer

The manufacturer submitted a cost-minimization analysis comparing the drug acquisition cost of Fp MDPI with a market share weighted average drug acquisition cost of two other Health Canada-approved Fp inhalers (Fp Diskus and Fp HFA) in the base-case analysis. As a secondary analysis, the same approach was conducted comparing Fp MDPI with all other available ICSs.⁴ The analysis was conducted from the perspective of a Canadian public health care payer over a one-year time horizon, with drug prices for comparators obtained from the Ontario Public Drug Plan formulary. The manufacturer justified the use of a cost-minimization analysis based on a claim of similar efficacy and safety with other ICS inhalers supported by a head-to-head randomized controlled trial comparing Fp MDPI to Fp HFA, as well as a network meta-analysis comparing Fp MDPI with other ICS inhalers.⁴

The manufacturer's base case used utilization data from several provinces (i.e., Manitoba, Quebec, New Brunswick, and Nova Scotia) to inform the following assumptions: the percentage utilization of available dosages of each medication, the average number of daily inhalations for each, and the percentage of market share of each individual ICS.⁴ The average number of daily inhalations was used to calculate the average yearly drug cost of

the ICS, while the per cent utilization of each dosage was used to calculate a weighted average cost of each ICS in a particular comparison. The manufacturer assumed that utilization for Fp MDPI was the same as other Fp products due to the lack of utilization data for Fp MDPI. Utilization data for Fp HFA and recommended number of doses for Fp Diskus were applied to Fp MDPI to estimate its expected costs using the approach described above.⁴ The percentage market share for each medication was multiplied by the weighted average cost of each ICS, excluding Fp MDPI, and their annual medication costs were then combined to obtain a market share weighted average cost. This final step was conducted to compare the costs of Fp MDPI with all Fp products combined, as well as all ICS inhalers combined.

The manufacturer reported that Fp MDPI (\$547.61) was associated with an annual cost savings of \$190.95 per patient per year when compared with a market share weighted average of Fp HFA and Fp Diskus (\$738.56; a 26% reduction in drug costs). A scenario analysis comparing Fp MDPI with Fp resulted in an annual cost savings of \$107.51 versus Fp Diskus (\$655.12; a 16% reduction in drug costs), and an annual cost savings of \$196.18 versus Fp HFA (\$743.79; a 26% reduction in drug costs).⁴

Sensitivity analyses were conducted to determine the impact of changing the number of inhalations from the utilization average to the recommended number of inhalations, the weighted average among all inhalers, and the highest and lowest variation for all Fp inhalers. Annual cost savings were observed for Fp MDPI in all scenarios (Appendix 1).⁴

In the secondary analysis comparing Fp MDPI with all ICS inhalers, including non-Fp ICS treatments, annual cost savings were observed in comparison to all comparators, ranging from \$0.29 per patient versus mometasone furoate (\$497.25 versus \$497.54; a 0.06% reduction in drug costs) to \$232.17 per patient versus Fp HFA (\$497.54 versus \$729.42; a 32% reduction in drug costs).⁴ When compared with the market share weighted cost of all ICS inhalers, Fp MDPI had an annual cost savings per patient of \$193.15 (\$497.25 versus \$690.40; a 28% reduction in drug costs).

Key Limitations

Weighted comparison: The availability and cost of each treatment option may differ between provinces, and the claims data used to obtain the estimates of utilization, average daily doses and market share was only available from certain provinces and does not reflect all jurisdictions taking part in the CADTH Common Drug Review process. Additionally, no utilization information was available for Fp MDPI; thus, there is uncertainty as to how it will be used in clinical practice. As such, the use of a weighted approach based on utilization data from several provinces is not considered appropriate for the base-case analysis. A non-weighted cost comparison of available dosages with the recommended daily dose obtained from the product monograph was considered more appropriate for the base case; an approach using utilization data could have been considered in a scenario analysis.

Issues for Consideration

 CADTH clinical reviewers identified limitations with the phase II studies presented in support of establishing comparative safety and efficacy between Fp MDPI and Fp Diskus, and noted that there is a degree of uncertainty regarding the dose equivalency and efficacy equivalency of Fp MDPI and Fp Diskus. Furthermore, the manufacturersubmitted network meta-analysis comparing Fp MDPI against placebo and other available ICSs for the treatment of asthma in Canada was identified to have several limitations that limit the generalizability and applicability of the network meta-analysis, As a

result, CADTH clinical reviewers concluded that there is limited comparative evidence for the use of Fp MDPI versus alternative ICS therapies.

- As indicated in the CADTH Clinical Report, Fp MDPI was reviewed as a "stand-alone" new drug submission for a "second entry" drug by Health Canada; thus, equivalence with a comparator was not a consideration of the review as Fp MDPI was not considered a generic of Fp Diskus. The product monograph for Fp MDPI recommends starting doses for patients based on the patients' asthma severity, and if the patient's current ICS dose is low, medium, or high, then they may switch to the respective starting doses, which are the low (55 mcg), medium (113 mcg), and high (232 mcg) doses of Fp MDPI. Health Canada stated that this was based on the inclusion criteria and the patient population in the pivotal phase III clinical trials.
- Feedback from the CDR clinical expert noted that prescribers unfamiliar with the dosing of Fp MDPI may prescribe double the dose, or that patients who are switching treatment may take double the dose, in order to match the amount of Fp HFA or Fp Diskus typically prescribed for severe asthma. Should this occur, Fp MDPI would no longer be cost saving on a per-patient basis and would incur additional costs. As more daily doses per inhaler would result, this may lead to increased costs associated with dispensing fees as there are fewer doses per inhaler for Fp MDPI than for some other agents (including Fp HFA).
- The publicly available price for comparators varies across the provinces (Table 6), which may impact the manufacturer's estimated cost savings.
- The confidential nature of negotiated effective price for pharmaceuticals means that CDR is unable to assess the impact of potential lower prices of comparators on the results.

Results/Conclusions

CDR identified limitations with the submitted cost comparison of Fp MDPI with other ICS treatments currently available in Canada, primarily related to the clinical data. The CDR clinical reviewers noted there is limited comparative effectiveness between Fp MDPI and other ICS treatments, and a degree of uncertainty regarding the dose equivalency and efficacy equivalency of Fp MDPI and Fp Diskus, given the data that was required for regulatory approval. As such, the assessment of comparative costs is highly uncertain.

Based on product monograph recommended dosing regimens, at the submitted price of \$16.96 for 55 mcg, \$30.96 for 113 mcg, and \$48.15 for 232 mcg per 60 dose MDPI (\$206 to \$586 per year), Fp MDPI may be less costly than currently available ICS treatments (\$124 to \$1,331; see Table 1) based on publicly available prices at assumed relative low, medium, and high doses. The cost comparison is based on publicly available comparator

prices, if price negotiations have occurred, this will affect any anticipated cost savings for Fp MDPI.

Cost Comparison Table

Clinical experts have deemed the comparator treatments presented in Table 1 to be appropriate. Comparators may be recommended (appropriate) practice versus actual practice. Comparators are not restricted to drugs, but may be devices or procedures. Costs are manufacturer list prices, unless otherwise specified. Existing Product Listing Agreements are not reflected in the table and as such may not represent the actual costs to public drug plans.

Table 1: CDR Cost Comparison Table of Inhaled Corticosteroids for the Treatment of Asthma

Drug/Comparator	Strength	Dosage Form	Price (\$)	Price/Dose (\$)	Recommended Dosage	Daily Drug Cost (\$)	Annual Drug Cost (\$)
Fluticasone propionate (Aermony RespiClick)	55 mcg 113 mcg 232 mcg	MDPI (60 doses)	16.9560 ^ª 30.9600 ^ª 48.1500 ^ª	0.2826 ^ª 0.5160 ^ª 0.8025 ^ª	55 mcg or 113 mcg or 232 mcg twice daily	0.57 1.03 1.61	206 377 586
Inhaled Corticoster	roids	,		-		•	
Fluticasone propionate (Flovent Diskus)	100 mcg 250 mcg 500 mcg	MDPI (60 doses)	24.8300 ^b 42.8220 65.5400	0.4138 0.7137 1.0923	100 mcg to 500 mcg twice daily	0.83 to 2.18	302 to 797
Fluticasone propionate (Flovent HFA)	50 mcg 125 mcg 250 mcg	MDI (120 doses)	24.8300 42.8200 85.6400	0.2069 0.3568 0.7137	100 mcg to 500 mcg twice daily	0.83 to 2.85	302 to 1,042
Fluticasone furoate (Arnuity Ellipta)	100 mcg 200 mcg	MDPI (30 doses)	38.5800 77.1600	1.2860 2.5720	100 mcg or 200 mcg once daily	1.29 to 2.57	469 to 939
Mometasone furoate (Asmanex Twisthaler)	200 mcg 400 mcg	MDPI (60 doses)	37.0560 74.1240	0.6176 1.2354	200 mcg or 400 mcg once daily	0.6176 to 1.2354	225 to 451
Budesonide (Pulmicort Turbuhaler)	100 mcg 200 mcg 400 mcg	MDPI (200 doses)	31.9200 65.2000 94.9400	0.1596 0.3260 0.4747	200 mcg to 400 mcg twice daily	0.64 to 0.95	233 to 347
Budesonide (Pulmicort Nebuamp)	0.125 mg/mL 0.25 mg/mL 0.5 mg /mL	Suspension for inhalation	0.2285 0.4573 0.9118	0.2285 0.4573 0.9118	1 mg to 2 mg twice daily	0.69 to 3.65	250 to 1,331
Beclomethasone dipropionate (QVAR)	50 mcg 100 mcg	MDI (200 doses)	33.9700 67.7400	0.1699 0.3397	50 mcg to 400 mcg twice daily	400 mcg 1.35	
Ciclesonide (Alvesco)	100 mcg 200 mcg	MDI (120 doses)	46.9200 77.6400	0.3910 0.6470	100 mcg to 400 mcg twice daily	0.78 to 2.59	285 to 945

Drug/Comparator	Strength	Dosage Form	Price (\$)	Price/Dose (\$)	Recommended Dosage	Daily Drug Cost (\$)	Annual Drug Cost (\$)
Leukotriene Recep	tor Antagonists	(LTRA)					
Montelukast (Singulair, generics)	4 mg 5 mg 10 mg	Chew Tablet Chew Tablet Tablet	0.2758 1.2075 1.7735	1.2075 1.7735	Age 6 to14: 5 mg daily Age 15+: 10 mg daily	1.77 to 2.48	647 to 906

CDR = CADTH Common Drug Review; HFA = hydrofluoroalkane; MDI = metered dose inhaler; MDPI = multidose dry powder inhaler.

Note: All prices are from the Ontario Drug Benefit Formulary (accessed May 3 2018), unless otherwise indicated, and do not include dispensing fees. ^a Based on Manufacturer's CDR Submission.²

^b Price obtained from Saskatchewan Online Formulary Database.⁵



Appendix 1: Reviewer Worksheets

Table 2: Summary of Manufacturer's Submission

Drug product	fluticasone propionate (Aermony RespiClick)						
Treatment	55 mcg, 113 mcg, or 232 mcg twice daily						
Comparator(s)	Other available Fp products Other ICS (secondary analysis)						
Study Question	What are the drug costs of Aermony RespiClick in comparison to the other available fluticasone propionate products and inhaled corticosteroids?						
Type of Economic Evaluation	Cost-minimization analysis						
Target Population	Patients aged 12 years and older with persistent asthma						
Perspective	Ontario Ministry of Health and Long-Term Care						
Outcome(s) Considered	Drug cost						
Key Data Sources							
Cost	Drug costs were obtained from the Ontario Drug Benefit Formulary						
Clinical Efficacy/Harms	 A phase III RCT comparing the manufacturer's drug with another fluticasone propionate product (Flovent HFA) A manufacturer-sponsored network meta-analysis comparing Fp MDPI with ICS treatments available in Canada 						
Utilization Data	IMS Health (MAT data Q2-Q4 2016 and Q1 2017)						
Time Horizon	1 year						
Results for Manufacturer's Base Case	 When compared with the market share weighted average costs of available Fp inhalers, Fp MDPI was cost saving (\$547.61 vs. \$738.56; 26% reduction in drug costs). Annual savings per patient versus Fp Diskus (Flovent Diskus) and Fp HFA (Flovent HFA) of \$107.51 (16% reduction in drug costs) and \$196.18 (26% reduction in drug costs), respectively. When using the recommended number of daily inhalations in place of an estimate based on utilization data, the annual cost savings versus Fp Diskus and Fp HFA of \$67.20 (12% reduction in drug costs) and \$302.50 (38% reduction in drug costs), respectively. When compared with all other inhaled corticosteroids, the use of Fp MDPI resulted in annual cost savings per patient ranging from \$0.29 to \$232.17, and cost savings of \$193.15 (\$497.25 vs. 690.40; 29% reduction in drug costs) when compared with the market share weighted average cost of all ICS inhalers combined. 						

Fp = fluticasone propionate; HFA = hydrofluoroalkane; ICS = inhaled corticosteroid; MDPI = multidose dry powder inhaler; RCT = randomized controlled trial. Source: Manufacturer's Pharmacoeconomic Submission.⁴

Manufacturer's Results

The manufacturer submitted a cost-minimization analysis comparing the cost of Fp MDPI with a market share weighted average of two other Health Canada-approved Fp inhalers (Fp Diskus and Fp HFA) in the base-case analysis, as well as a secondary analysis comparing Fp MDPI with all other available ICS inhalers.⁴ The detailed results of the base-case analysis are provided in Table 3.

				Treatm	ent Acquisit	tion Costs	Difference vs. Fp MDPI		
Treatment	Market Shares (%)	Unit Cost	Units per Day	Daily Cost	Monthly Cost	Annual Cost	Monthly Cost	Annual Cost (% Reduction)	
Fp MDPI (Aermony RespiClick)	_	\$0.6668	2.25	\$1.50	\$45.63	\$547.61	—	-	
Other Fp Inhalers									
Fp Diskus (Flovent Diskus)	5.9%	\$0.7588	2.4	\$1.79	\$54.59	\$655.12	-\$8.96	–\$107.51 (16.41%)	
Fp HFA (Flovent HFA)	94.1%	\$0.5406	3.8	\$2.04	\$61.98	\$743.79	-\$16.35	-\$196.18 (26.38%)	
Weighted Fp (Flovent Diskus and Flovent HFA)	100.00%	-	-	\$2.02	\$61.55	\$738.56	-\$15.91	–\$190.95 (25.85%)	

Table 3: Results of Manufacturer's Base-Case Analysis

Fp = fluticasone propionate; HFA = hydrofluoroalkane; MDPI = multidose dry powder inhaler; vs. = versus.

Source: Manufacturer's Pharmacoeconomic Submission.⁴

In a scenario analysis, the manufacturer used the product monograph recommended number of daily inhalations to inform the number of units per day instead of utilization data. The results of this analysis are provided in Table 4.

Table 4: Results of Manufacturer's Analysis Using the Recommended Number of Daily Inhalations

				Treatme	nt Acquisiti	on Costs	Differen	ce vs. Fp MDPI	
Treatment	Market Shares	Unit Cost	Units/ Day	Daily Cost	Monthly Cost	Annual Cost	Monthly Cost	Annual Cost (% of Reduction)	
Fp MDPI (Aermony RespiClick)	-	\$0.6668	2.0	\$1.33	\$40.56	\$486.73	-	-	
Other Fp Inhalers									
Fp Diskus (Flovent Diskus)	5.9%	\$0.7588	2.0	\$1.52	\$46.16	\$553.93	-\$5.60	-\$67.20 (-12.13%)	
Fp HFA (Flovent HFA)	94.1%	\$0.5406	4.0	\$2.16	\$65.77	\$789.23	-\$25.21	-\$302.50 (-38.33%)	
Weighted Fp (Flovent Diskus and Flovent HFA)	100.00%	-	-	\$2.12	\$64.61	\$775.36	-\$24.05	-\$288.63 (-37.23%)	

Fp = fluticasone propionate; HFA = hydrofluoroalkane; MDPI = multidose dry powder inhaler; vs. = versus.

Source: Manufacturer's Pharmacoeconomic Submission.⁴

In another scenario considering all available ICS inhalers currently covered in Canada, Fp MDPI was still associated with annual cost savings compared with each ICS individually, as well as to the market share weighted average of all ICS inhalers combined. The results of this analysis are provided in Table 5.

				Trea	itment Acqu	isition Costs	Difference	vs. Fp MDPI
Treatment	Market Shares	Unit Cost	Units per Day	Daily Cost	Monthly Cost	Annual Cost	Monthly Cost	Annual Cost (% of Reduction)
Fp MDPI (Aermony RespiClick)	-	\$0.6668	2.04	\$1.36	\$41.44	\$497.25	-	-
Other ICS Inhalers								
Fp Diskus (Flovent Diskus)	4.5%	\$0.6820	2.4	\$1.79	\$54.59	\$655,12	-\$13.16	-\$157.87 (-24.10%)
Fp HFA (Flovent HFA)	71.2%	\$0.4629	3.8	\$2.00	\$60.79	\$729,42	-\$19.35	-\$232.17 (-31.83%)
Ciclesonide (Alvesco)	12.2%	\$0.5544	2.8	\$1.68	\$51.07	\$612,79	-\$9.63	-\$115.54 (-18.85%)
Fluticasone furoate (Arnuity Ellipta)	0.4%	\$1.6383	1.0	\$1.76	\$53.57	\$642,88	-\$12.14	-\$145.63 (-22.65%)
Mometasone furoate (Asmanex Twisthaler)	2.3%	\$0.9478	1.4	\$1.36	\$41.46	\$497,54	-\$0.02	-\$0.29 (-0.06%)
Budesonide (Pulmicort Turbuhaler)	6.8%	\$0.3191	4.5	\$1.46	\$44.50	\$534,01	-\$3.06	-\$36.76 (-6.88%)
Beclomethasone dipropionate (QVAR)	2.7%	\$0.2912	5.8	\$1.73	\$52.74	\$632,94	-\$11.31	-\$135.69 (-21.44%)
All ICS inhalers combined	100.0%	-	-	\$1.89	\$57.53	\$690,40	-\$16.10	–\$193.15 (–27.98%)

Table 5: Results of Manufacturer's Analysis Comparing Fp MDPI With All ICS Inhalers

Fp = fluticasone propionate; HFA = hydrofluoroalkane; ICS = inhaled corticosteroid; MDPI = multidose dry powder inhaler; vs. = versus. Source: Manufacturer's Pharmacoeconomic Submission.⁴

CADTH Common Drug Review Results

In addition to the CDR cost table (Table 1), CDR tabulated the annual cost per person of all comparator ICS inhalers across CDR member jurisdictions where data were available (Table 6).

Treatment		Member Jurisdictions													
	BC	AB	SK	МВ	ON	NB	NS	PE	NL	YK	NT	NU	NIHB	DND	VAC
Fluticasone propionate (Flovent Diskus)	184 to 861	302 to 797	302 to 797	297 to 781ª	302 to 797	302 to 797	302 to 797	302 to 797ª	328 to 865	302 to 797 ^a	302 to 797 ^a	302 to 797 ^a	NPA	NPA	NPA
Fluticasone propionate (Flovent HFA)	326 to 1,125	302 to 1,042	302 to 1,042	296 to 1,021ª	302 to 1,042	302 to 1,042	302 to 1,042	302 to 1,042 ^a	328 to 1,130	302 to 1,042ª	302 to 1,042 ^a	302 to 1,042ª	NPA	NPA	NPA
Ciclesonide (Alvesco)	308 to 1,011	284 to 945	284 to 1,020	282 to 931ª	285 to 1,020	285 to 945	285 to 945	285 to 944 ^a	306 to 945	285 to 944 ^a	285 to 944 ^a	285 to 944 ^a	NPA	NPA	NPA
Fluticasone furoate (Arnuity Ellipta)	507 to 1,014	469 to 939	469 to 939	463 to 926ª	469 to 939	469 to 939	469 to 939	469 to 939 ^a	513 to 1,026	469 to 939 ^a	469 to 939ª	469 to 939 ^a	NPA	NPA	NPA
Mometasone furoate (Asmanex Twisthaler)	223 to 445	225 to 451	225 to 451	220 to 440ª	225 to 451	225 to 451	224 to 449	225 to 451ª	245 to 489	225 to 451ª	225 to 451ª	225 to 451ª	NPA	NPA	NPA
Budesonide (Pulmicort Turbuhaler)	252 to 374	232 to 347	233 to 347	228 to 339 ^ª	233 to 347	233 to 347	233 to 347	233 to 347 ^a	248 to 368	233 to 347ª	233 to 347ª	233 to 347ª	NPA	NPA	NPA
Beclomethasone dipropionate (QVAR)	85 to 387	85 to 327	85 to 327	90 to 359 ^a	90 to 359	90 to 359	90 to 359	90 to 359 ^ª	97 to 390	90 to 359ª	90 to 359ª	90 to 359ª	NPA	NPA	NPA

Table 6: Annual Price (\$) per Patient of Comparator Inhaled Corticosteroid Inhalers Across CDR Member Jurisdictions

AB = Alberta; BC = British Columbia; CDR = CADTH Common Drug Review; DND = Department of National Defence; HFA = hydrofluoroalkane; MN = Manitoba; NIHB = Non-Insured Health Benefits program; NL = Newfoundland and Labrador; NPA = no price available; NS = Nova Scotia; NT = Northwest Territories; ON = Ontario; PE = Prince Edward Island; SK = Saskatchewan; VAC = Veterans Affairs Canada; YK = Yukon.

Note: All prices listed are formulary prices obtained from IQVIA DeltaPA unless otherwise noted.⁶ Actual price paid by the plan may vary.

^a Wholesale acquisition price from IQVIA DeltaPA⁶ (no formulary price for the jurisdiction).

References

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- FLOVENT[®] HFA (fluticasone propionate inhalation aerosol): 50, 125, and 250 mcg/metered dose; FLOVENT[®] DISKUS[®] (fluticasone propionate powder for inhalation): 100, 250, AND 500 mcg/blister [product monograph] [Internet]. Mississauga (ON): GlaxoSmithKline Inc.; 2016. [cited 2018 Feb 28]. Available from: https://pdf.hres.ca/dpd_pm/00035198.PDF
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