Common Drug Review
Pharmacoeconomic Review Report

December 2015

Drug	Inhaled fluticasone furoate (Arnuity Ellipta) (100 mcg and 200 mcg)
Indication	Once-daily maintenance treatment of steroid-responsive bronchial asthma in patients aged 12 years and older
Listing request	As per indication
Dosage form(s)	Dry powder for oral inhalation, 100 mcg/200 mcg
NOC date	21-09-2015
Manufacturer	GlaxoSmithKline Inc.

Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

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ABBREVIATIONS

CDR	CADTH Common Drug Review
ICS	inhaled corticosteroid
LABA	long-acting beta2-adrenergic agonist
ODB	Ontario Drug Benefit

SUMMARY

Background

Fluticasone furoate (FF; Arnuity Ellipta) is an inhaled corticosteroid (ICS) indicated for the once-daily maintenance treatment of steroid-responsive bronchial asthma in patients aged 12 years and older.[1] The recommended dose of FF is 100 mcg or 200 mcg once daily, delivered from a dry powder breath-actuated inhaler, Ellipta. FF is available as a 30-dose inhaler providing dry powder for inhalation at two strengths: 30 actuations of 100 mcg ([redacted]) and 30 actuations of 200 mcg ([redacted]). Based on the submitted confidential price and recommended daily dose, the daily cost of FF 100 mcg is [redacted] and the daily cost of 200 mcg is [redacted].

Summary of the Economic Analysis Submitted by the Manufacturer

The manufacturer submitted a cost analysis comparing the drug costs of FF 100 mcg and FF 200 mcg versus currently available ICS monotherapies: fluticasone propionate (FP), ciclesonide (CIC), mometasone furoate (MF), budesonide (BUD), and beclomethasone dipropionate (BDP).[2] Four comparisons were performed: FF 100 mcg versus FP 250 mcg, FF 100 mcg versus a claim-weighted average cost based on all available ICS monotherapies, FF 200 mcg versus FP 500 mcg, and FF 200 mcg versus a claim-weighted average cost based on all available ICS monotherapies. The cost analysis was conducted from the Canadian public payer perspective, based on a one-year time frame. Only drug costs were considered. They were obtained from the Ontario Drug Benefit (ODB, January 2015). All ODB asthma-related claims data (January 2014 to November 2014) for ICSs and ICS/LABA combinations were obtained from IMS Brogan Rx Dynamics.

For the comparison of FF 100 mcg versus FP 250 mcg twice daily, the assumption of similar efficacy was based on clinical trial FFA-059,[3] which reported similar efficacy based on the primary outcome, namely change in trough FEV_1 from baseline to 24 weeks. The assumption of similar efficacy of FF 200 mcg daily compared with FP 500 mcg twice daily was based on clinical trial HZA-829,[4] which reported non-inferiority of FF 200 mcg compared with FP 500 mcg twice daily on the primary outcome (i.e., change in trough FEV_1 from baseline to 24 weeks). For the comparison of FF versus claim-weighted ICS monotherapies, FF 100 was compared with low- or medium-dose ICSs, and FF 200 mcg was compared with high-dose ICSs (Table 5). Similar efficacy and safety was assumed based on a systematic review by Shepherd et al.,[5] which reported no significant differences across comparable doses of ICSs.

The manufacturer calculated drug costs based on the initial treatment (FF 100 mcg or FF 200 mcg daily, or FP 250 mcg or FP 500 mcg twice daily) and assumed that a proportion of patients (59% based on a study by Chapman et al.),[6] regardless of initial treatment, would require step-up to an ICS/LABA (when symptoms deteriorate). The cost of step-up treatment was estimated as a claim-weighted average cost of both ICS/LABA fixed-dose and open-dose combinations.

Key Limitations

- **No head-to-head evidence reported comparing FF 100 mcg with FP 250 mcg:** Study FFA-059 was the only phase 3 clinical trial that included FF 100 mcg once daily and FP 250 mcg twice daily, with placebo as comparator. The primary treatment comparison was FF 100 mcg once daily versus placebo**.** Additionally**,** FP 250 mcg twice daily was compared with placebo for all efficacy and safety end points. However, as discussed in the CDR clinical review, limited conclusions can be made on the comparison between FP and FF as no formal statistical analyses comparing FF and FP were done.

- **Uncertainty regarding long-term, non-inferiority of FF 200 mcg versus FP 500 mcg:** Study HZA-829 is the only head-to-head comparison of FF 200 mcg and FP 500 mcg over a 24-week period. While no study captured data at both 12 weeks and 24 weeks, based on results from the 12-week study (HZA-827) and the 24-week study (HZA-829), it appears that the benefits of FF may plateau after 12 weeks. The study period for HZA-829 was 24 weeks, and it is uncertain whether the non-inferiority of FF 200 mcg extends beyond this time period.
- **Uncertain comparative efficacy and safety of FF versus other ICSs:** While there is evidence that different ICS therapies offer similar efficacy across outcomes including lung function, symptoms, use of rescue medications, and exacerbation rates,[5] the manufacturer did not provide any direct or indirect evidence to support the comparative efficacy and safety of FF relative to other available ICS monotherapies beyond FP. Furthermore, uncertainty remains with respect to the dose equivalency of FF relative to FP and other ICSs. As mentioned above, no direct comparison was reported to support the equivalence of FF 100 mcg compared with FP 250 mcg twice daily or other ICSs, and only one study (HZA-829) supports the non-inferiority of FF 200 mcg compared with FP 500 mcg.[4] Available information suggesting the clinical equivalence of ICS therapies do not include FF 100 mcg or FF 200 mcg.[7]
- **Inappropriate weights:** Claims data from ODB (January 2014 to November 2014) obtained from IMS Brogan Rx Dynamics were used to calculate market shares for both ICSs and ICS/LABA combinations, which were then used to estimate their weighted average costs. Since the average number of daily doses or supply days per claim varies across various ICSs and ICS/LABAs, the percentages of claims will very likely be different from actual market shares, which are defined by volume (number of daily doses/units). Therefore, it would have been more appropriate to use the number of units for estimating weighted average costs of ICSs and the weighted average costs of ICS/LABAs.

  Additionally, in the variability analysis, the savings reported by the manufacturer arising from the cost differential between FF (100 mcg or 200 mcg) and the weighted average cost will only be realized should FF (100 mcg or 200 mcg) replace existing comparator doses in the proportion assumed by the manufacturer, based on current claims data. This is highly unlikely, given the fact that existing comparators, especially leading ones, have a market advantage compared with a new entrant. Thus, would have been more appropriate to compare the cost of FF (100 mcg or 200 mcg) with each comparator dose individually.

Results and Conclusions

The lack of comparative clinical studies and the absence of a well-conducted indirect comparison limits the comparison of FF with other ICS monotherapies.

At the confidential submitted price of [redacted] per day for FF 100 mcg and [redacted] per day for FF 200 mcg, FF is less costly than FP ([redacted] daily, FP 250 mcg; [redacted] daily, FP 500 mcg) at respective low/high doses. When compared with low-dose ICSs, FF 100 mcg is more costly (additional cost from [redacted] to [redacted] per patient annually). When compared with medium-dose ICSs, the cost of FF 100 mcg is the same as BUD 400 mcg (800 mcg daily), but lower than other medium-dose ICSs (savings ranging from [redacted] to [redacted] per patient annually). When comparing FF 200 mcg with high-dose ICSs, FF 200 mcg is more costly than BUD 400 mcg ([redacted] per patient annually, 1,200 mcg daily), but is cost saving relative to other high-dose ICSs (savings ranging from [redacted] to [redacted] per patient annually).

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 also 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: COST-COMPARISON TABLE FOR ICS AND ICS/LABA COMBINATIONS FOR ASTHMA

Drug/Comparator	Strength (mcg)	Dosage Form	Price ($)	Price/ Dose ($)	Recommended Daily Use (Dosages in mcg)	Daily Drug Cost ($)	Annual Drug Cost ($)
FF (Arnuity Ellipta)	100 200	Inhalant pwd (30 doses)	[redacted]	[redacted]	100 or 200 once daily	[redacted]	[redacted]
ICS							
FP (Flovent Diskus)	250 500	Inhalant pwd (60 doses)	41.2800 64.2000	0.688 1.0700	250 or 500 twice daily	1.38 2.14	502.24 781.10
FP (Flovent HFA)	50 125 250	MDI (120 doses)	23.9300 41.2800 82.5400	0.1994 0.3440 0.6878	100 or 250 or 500 twice daily	0.80 1.38 2.75	291.12 502.24 1004.24
Ciclesonide (Alvesco)	100 200	MDI (120 doses)	45.5400 75.2800	0.3795 0.6273	100 or 200 twice daily	0.76 1.25	277.04 457.95
Mometasone furoate (Asmanex Twisthaler)	200 400	MDI (60 doses)	35.4800 70.9600	0.5913 1.1827	200 or 400 once daily	0.59 1.18	215.84 431.67
Budesonide (Pulmicort Turbuhaler)	100 200 400	Inhalant pwd (200 doses)	31.2700 63.8600 93.0000	0.1564 0.3193 0.4650	100 or 200 or 400 twice daily	0.31 0.64 0.93	114.14 233.09 339.45
Beclomethasone dipropionate (QVAR)	50 100	Metered Dose Aero Inhaler (200 doses)	31.1900 62.2000	0.1560 0.3110	50 or 100 twice daily	0.31 0.62	113.84 227.03

Drug/Comparator	Strength (mcg)	Dosage Form	Price ($)	Price/ Dose ($)	Recommended Daily Use (Dosages in mcg)	Daily Drug Cost ($)	Annual Drug Cost ($)
ICS/LABA Combinations							
Budesonide/ Formoterol (Symbicort Turbuhaler)	100/6 200/6	Inhalant pwd (120 doses)	64.5600 83.8800	0.5380 0.6990	100/6 or 200/6 twice daily	1.08 1.40	392.74 510.27
FP/Salmeterol (Advair)	125/25 250/25	MDI (120 doses)	97.4299 138.3141	0.8119 1.1526	250/50 or 500/50 twice daily	3.25 4.61	1185.40 1682.82
FP/Salmeterol (Advair Diskus)	100/50 250/50 500/50	Inhalant pwd (60 doses)	81.3929 97.4299 138.3141	1.3565 1.6238 2.3052	100/50 or 250/50 or 500/50 twice daily	2.71 3.25 4.61	990.28 1185.40 1682.82
Mometasone furoate/ Formoterol fumarate (Zenhale)	50/5 100/5 200/5	MDI (120 doses)	70.5600 89.5560 108.5400	0.5880 0.7463 0.9045	100/10 or 200/10 or 400/10 or twice daily	2.35 2.99 3.62	858.48 1089.60 1320.57

ICS = inhaled corticosteroid; LABA = long-acting beta2-agonist; pwd = powder; MDI = metered dose inhaler.
[a] Manufacturer's confidential submission price.
Source: Ontario Drug Benefit Formulary (accessed August 2015) unless otherwise indicated.

APPENDIX 1: PRICE REDUCTION ANALYSIS

Assuming fluticasone furoate (FF) is similar in terms of clinical efficacy and harms outcomes compared with ICS monotherapies as assumed by the manufacturer, CDR calculated the price reduction that would be required for FF 100 mcg and 200 mcg to be equivalent to the least expensive inhaled corticosteroid (ICS) comparator dose currently reimbursed by the Ontario Drug Benefit.

As shown in Table 2, compared with the least expensive **low-dose ICS** (beclomethasone dipropionate 50 mcg for total daily dosage of 100 mcg), the price of FF 100 mcg would need to be reduced by [redacted]. However, [redacted] would be needed if compared with the price of the least expensive **medium-dose ICS** (budesonide 400 mcg for total daily dosage of 800 mcg). The price of FF 200 mcg would need to be reduced by [redacted] to equal that of the least expensive **high-dose ICS** (budesonide 400 mcg for total daily dosage of 1,200 mcg) at [redacted] per day.

TABLE 2: CADTH COMMON DRUG REVIEW PRICE REDUCTION SCENARIOS FOR FLUTICASONE FUROATE

Current Price[a] ($)	Scenario	Reduced Price[b] ($)	% Price Reduction
FF 100 mcg			
[redacted]	Price reduction needed to equal the price of the least expensive **low-dose ICS** (beclomethasone dipropionate) 50 mcg for total daily dose of 100 mcg)	[redacted]	[redacted]
[redacted]	Price reduction needed to equal the price of the least expensive **medium-dose ICS** (budesonide 400 mcg for total daily dose of 800 mcg)	[redacted]	[redacted]
FF 200 mcg			
[redacted]	Price reduction needed to equal the price of the least expensive **high-dose ICS** (budesonide 400 mcg for total daily dose of 1,200 mcg)	[redacted]	[redacted]

FF = fluticasone furoate; ICS = inhaled corticosteroid.
[a] Manufacturer-submitted price.
[b] Daily cost does not include markup or dispensing fees.

APPENDIX 2: REVIEWER WORKSHEETS

TABLE 3: SUMMARY OF MANUFACTURER'S SUBMISSION

Drug Product	**FF (Arnuity Ellipta) 100 mcg and 200 mcg**
Treatment	100 mcg or 200 mcg once daily
Comparators	FF 100 mcg vs. FP via Diskus 250 mcg twice daily FF 200 mcg vs. FP via Diskus 500 mcg twice daily
Study Question	What is the economic impact of FF (100 mcg and 200 mcg) compared with: 1) FP (250 mcg/500 mcg), and 2) a utilization-weighted cost based on currently available ICS monotherapies in Canada?
Type of Economic Evaluation	Cost-comparison (drug costs only)
Target Population	Patients with steroid-responsive bronchial asthma aged ≥ 12 years
Perspective	Canadian public payer
Outcomes Considered	Trough FEV_1 (primary efficacy end point) Rescue-free 24-hour periods (nominated secondary efficacy end point) Evening PEF (secondary efficacy end point) Morning PEF (secondary efficacy end point) Symptom-free 24-hour periods (secondary efficacy end point) AQLQ +12 (secondary efficacy end point)
Key Data Sources	
Cost	ODB (2014), IMS Brogan Rx Dynamics (2010–2014)
Clinical Efficacy	Manufacturer-sponsored clinical trials (FFA-687, FFA-059, HZA-827, FFA-496, HZA-829)
Harms	Manufacturer-sponsored clinical trials
Time Horizon	One year
Results for Base Case	• Use of FF 100 mcg resulted in a lower annual total cost per patient ([redacted]) than use of FP 250 mcg ([redacted]) by $[redacted]. • Use of FF 200 mcg resulted in a lower annual total cost per patient ([redacted]) relative to the use of FP 500 mcg ([redacted]) by [redacted].

FEV_1 = forced expiratory volume in 1 second; FF = fluticasone furoate; FP = fluticasone propionate; ICS = inhaled corticosteroid; ODB = Ontario Drug Benefit; PEF = peak expiratory flow; vs = versus.

Manufacturer's Results

In the base case, fluticasone furoate 100 mcg once daily (FF 100 mcg) was compared with fluticasone propionate (FP) Diskus, one inhalation of 250 mcg twice daily (FP 250 mcg), and FF 200 mcg once daily was compared with fluticasone propionate Diskus, one inhalation of 500 mcg twice daily (FP 500 mcg). The cost of use of FF (100 mcg or 200 mcg) and FP (250 mcg or 500 mcg) was calculated based on the cost of the ICS (while the patient is symptom free) plus the cost of the step-up to an ICS plus long-acting beta2-agonist (LABA) when the patient experiences an exacerbation of symptoms. Based on a study by Chapman et al., (2008),[6] it is assumed that, on average, a patient is symptom free 41% of the time and has symptoms 59% of the time.

Based on these assumptions, the use of FF 100 mcg resulted in a lower annual total cost per patient ($626.22) than the use of FP 250 mcg ($695.37) by $69.16. The use of FF 200 mcg resulted in a lower annual total cost per patient ($770.42) relative to the use of FP 500 mcg ($813.84) by $43.42 (Table 4).

TABLE 4: MANUFACTURER'S BASE-CASE COST ANALYSIS

	FF 100 mcg vs. Comparator			FF 200 mcg vs. Comparator		
Scenarios	**Annual Cost ($) FF 100 mcg**	**Annual Cost ($) FP 250 mcg**	**Annual Cost Difference**	**Annual Cost ($) FF 200 mcg**	**Annual Cost ($) FP 500 mcg**	**Annual Cost Difference**
Base Case Symptom-free (41%) With symptoms (59%)	[redacted]	695.37 205.92 489.45	[redacted]	[redacted]	813.84 320.25 493.58	[redacted]
	FF 100	**Weighted Mix ICS**		**FF 200**	**Weighted Mix ICS**	
Weighted ICS dose Symptom-free (41%) With symptoms (59%)	[redacted]	665.58 174.75 490.83	[redacted]	[redacted]	906.65 409.82 496.83	[redacted]

FF = fluticasone furoate; FP = fluticasone propionate; ICS = inhaled corticosteroid; vs = versus.
Source: Adapted from the manufacturer's pharmacoeconomic submission and model.[8]

In addition to the base case, variability analyses were also presented, including cases with changes in the ICS costs, mix of ICSs, and number of inhalations per day based on Canadian Thoracic Society guidelines (Table 5).[7] When comparing the cost of using FF 100 mcg with the weighted average cost of low-/medium-dose ICSs currently used in the market place, the per-patient cost difference decreased slightly ([redacted] to [redacted]) (Table 4). Similar results were found for the cost difference of using FF 200 mcg compared with the weighted average cost of high-dose ICSs ([redacted] to [redacted] per patient). The results of other variability analyses also confirmed that the base-case cost savings results were robust.

TABLE 5: ICS MONOTHERAPIES INCLUDED IN THE LOW-/MEDIUM-DOSE AND HIGH-DOSE ICS COMPARISON

Comparator	Strength (mcg)	Total Daily Dose (mcg)
Low-/Medium-dose ICS		
FP (Flovent Diskus)	250	500
FP (Flovent HFA)	50 125	200 500
Ciclesonide (Alvesco)	100 200	200 400
Mometasone furoate (Asmanex Twisthaler)	200 400	200 400
Budesonide (Pulmicort Turbuhaler)	100 200 400	200 400 800
Beclomethasone dipropionate (QVAR)	50 100	100 200
High-dose ICS		
FP (Flovent Diskus)	500	1,000
FP (Flovent HFA)	250	1,000
Ciclesonide (Alvesco)	200	800
Budesonide (Pulmicort Turbuhaler)	400	1,200
Beclomethasone dipropionate (QVAR)	100	600

FP = fluticasone propionate; ICS = inhaled corticosteroid.
Source: Adapted from the manufacturer pharmacoeconomic submission.[2]

It should be noted that ICS claims data from ODB (January 2014 to November 2014) obtained from IMS Brogan Rx Dynamics were used to estimate market shares. Because the average number of doses or supply days per claim varies across various ICSs, the percentages of claims will likely be different from the actual market shares, which, by definition, are about volume (number of doses/units). Therefore, it would have been more appropriate to use the numbers of ICS units for estimating the weighted average cost of all ICSs in the low-, medium-, or high-dose categories.

CADTH Common Drug Review Results

As noted above, it would have been more appropriate to use the numbers of ICS units for estimating the weighted average costs of all low-, medium-, and high-dose ICS use. Similarly, to estimate the cost of step-up therapy to an ICS/LABA when the patient has symptoms, volume data instead of claims data should be used to estimate the weighted average cost of the step-up treatment due to symptoms. However, no reliable volume data are currently available for ICSs and ICS/LABA combinations. Additionally, the estimates of the unit costs of step-up therapy to fixed-dose combinations and open-dose combinations of the ICS/LABAs should be assumed to be the same, as there is no evidence to indicate differential costs associated with step-up therapy from FF, FP, or other ICSs.

In both the base-case scenario and the weighted ICS dose scenario (Table 4), it was assumed that 41% of patients remain symptom free based on the study by Chapman et al.,[6] although it is uncertain whether this assumption applies to this population. Further, as this applies equally regardless of initial ICS monotherapy, it is unclear why differences in step-up ICS/LABA treatment and costs would apply. Based on the manufacturer's analysis, the cost of step-up ICS/LABA is less for FF compared with FP. There is no justification for this assumption. In the absence of information on the need for step-up treatment by ICS, it would have been more appropriate to consider the annual cost of the drugs in all patients and compare FF 100 mcg and FF 200 mcg with individual ICSs.

When considering the comparison of FF to the weighted average cost of ICS (by dose), the results apply only when FF replaces the current comparators in the exact proportions considered, which is highly unlikely. Thus, it would have been more appropriate to compare FF 100 mcg (and FF 200 mcg) with individual ICSs.

When comparing FF with other ICSs, it is uncertain what would be appropriate doses for comparison. The lack of comparative analyses for FF 100 mcg versus FP 250 mcg exist, although it was shown that FF 200 mcg is not inferior to FP 500 mcg. Further, there is no comparative clinical information regarding how FF compares with other low-/medium-/high-dose ICS treatments. Given the uncertainty of equivalent dosages, it would have been reasonable to compare FF 100 with low and medium doses of other ICSs, and FF 200 mcg with high doses of other ICSs individually.

CDR compared the cost of treatments by dose level, per patient per year (Table 6). When compared with low-dose ICSs, FF 100 mcg is more costly — ranging from [redacted] up to [redacted] per patient per year. The cost of FF 100 mcg is lower than that of medium-dose ICS (cost savings ranging from [redacted] to [redacted] per patient per year). When comparing FF 200 mcg with high-dose ICSs, the cost savings per patient is greatest relative to FP HFA 250 mcg ([redacted]), followed by ciclesonide 200 mcg ($[redacted]), FP Diskus 500 mcg ($[redacted]), and beclomethasone dipropionate 100 mcg ($[redacted]), but will result in an additional cost relative to budesonide 400 mcg([redacted]).

TABLE 6: CADTH COMMON DRUG REVIEW ANALYSIS ON PRICE FOR FLUTICASONE FUROATE

Drug/Comparator	Strength (mcg)	Total Daily Dose (mcg)	Daily Drug Cost ($)[b]	Annual Drug Cost ($)	Annual Cost Differential with FF ($)
FF (Arnuity Ellipta)	**100**	**100**	[redacted]	[redacted]	**NA**
Low-Dose ICS – Compared with FF 100 mcg					
FP (Flovent HFA)	50	200	0.80	291.12	[redacted]
Ciclesonide (Alvesco)	100	200	0.76	277.04	[redacted]
Mometasone furoate (Asmanex Twisthaler)	200	200	0.59	215.84	[redacted]
Budesonide (Pulmicort Turbuhaler)	100 200	200 400	0.31 0.64	114.14 233.09	[redacted]
Beclomethasone dipropionate (QVAR)	50 100	100 200	0.31 0.62	113.84 227.03	[redacted]
Medium-Dose ICS – Compared with FF 100 mcg					
FP (Flovent Diskus)	250	500	1.38	502.24	[redacted]
FP (Flovent HFA)	125	500	1.38	502.24	[redacted]
Ciclesonide (Alvesco)	200	400	1.25	4,457.93	[redacted]
Mometasone furoate (Asmanex Twisthaler)	400	400	1.18	431.67	[redacted]
Budesonide (Pulmicort Turbuhaler)	400	800	0.93	339.45	[redacted]
High-Dose ICS – Compared with FF 200 mcg					
FF (Arnuity Ellipta)	**200**	**200**	[redacted]	[redacted]	**NA**
FP (Flovent Diskus)	500	1,000	2.14	781.10	[redacted]
FP (Flovent HFA)	250	1,000	2.75	1,004.24	[redacted]
Ciclesonide (Alvesco)	200	800	2.51	915.86	[redacted]
Budesonide (Pulmicort Turbuhaler)	400	1,200	1.40	509.18	[redacted]
Beclomethasone dipropionate (QVAR)	100	600	1.87	681.09	[redacted]

FF = fluticasone furoate; FP = fluticasone propionate; ICS = inhaled corticosteroid; NA = not applicable.
[a] Manufacturer-submitted price.
[b] Daily cost does not include markup or dispensing fees.

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