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Circular 024 / 14 1 September 2014

Dear Pharmacist,

The Medicines Management Programme (MMP) has completed a review of the prescribing of inhaler treatments for Asthma and Chronic Obstructive Pulmonary disease (COPD) and have presented guidance to GPs in recent weeks entitled 'Prescribing and Cost Guidance for Inhaled Medicines'. Separate guidance documents are issued for Asthma and COPD and both are published on www.hse.ie/yourmedicines.

The guidance documents outline in detail the treatment of Asthma and COPD based on international best practice guidelines, and contain useful information on dosing, inhaler device selection, and switching between devices. Information is also included on the associated costs of inhalers for Asthma and COPD, conveniently broken down according to therapeutic drug class into cost per device, per actuation, and typical cost per day.

Please find enclosed a copy of the communication that went to all GP prescribers for your information.

The HSE seeks your assistance in this initiative in explaining to patients the advantages of such an approach.

Yours sincerely,

Patrick Burke

Primary Care Reimbursement Service





11th August, 2014

Re: Prescribing and Cost Guidance for Inhaled Medicines

Dear Colleagues

I write to inform you that the Medicines Management Programme (MMP) has completed a review of the prescribing of inhaler treatments for Asthma and Chronic Obstructive Pulmonary disease (COPD) and we now present guidance entitled 'Prescribing and Cost Guidance for Inhaled Medicines'. Separate guidance documents are issued for Asthma and COPD and both are published on www.hse.ie/yourmedicines.

The guidance documents outline in detail the treatment of Asthma and COPD based on international best practice guidelines, and contain useful information on dosing, inhaler device selection, and switching between devices. Information is also included on the associated costs of inhalers for Asthma and COPD, conveniently broken down according to therapeutic drug class into cost per device, per actuation, and typical cost per day.

In 2013, expenditure on inhalers exceeded €07 million¹. Our analyses of 2013 reimbursement claims data concluded that approximately €0 million was spent on inhalers for patients with COPD, with the remaining €17 million spent on treating those with Asthma². There is a wide variation in the costs associated with inhaled medicines for Asthma and COPD, with some preparations costing cents per day and others exceeding €1.80 per day.

For your convenience, some of the main prescribing points for Asthma and COPD together with inhaler costs have been summarised in the two supplements enclosed herewith which are also available on www.hse.ie/yourmedicines.

As the Clinical Lead for the Medicines Management Programme I hope that our prescribing guidance on inhaled medicines for the treatment of Asthma and COPD will prove useful to prescribers. Changes in prescribing patterns in this area should enhance safe, effective and cost-effective prescribing which is the main aim of the programme.

I wish to thank you for your continued support with the Medicines Management Programme.

With best wishes

Prof Michael Barry

National Clinical Lead, Medicines Management Programme

http://www.hse.ie/yourmedicines

Michael Brusy.

¹ Expenditure estimates include ingredient cost, pharmacy fee, and tax, where applicable.

² It was assumed that patients 40 years or younger have Asthma, and patients older than 40 years have COPD.

Management of COPD in Clinical Practice



Patient category	1 st choice	treatment		Alternative treatment
GOLD 1-2 Category A Mild — moderate COPD with a low risk of exacerbations & less symptoms. FEV₁≥ 80% predicted	<u>or</u>	Eing beta ₂ agonist (SABA) E.g. salbutamol 100 µg PRN (Gerivent®, Salamol®, Salbul®, Ventolin®) Eing muscarinic antagonist (SAE.g. ipratropium 20 µg PRN (Atrovent®)	MA)	Long-acting muscarinic antagonist (LAMA) or Long-acting beta ₂ agonist (LABA) or SABA + SAMA
GOLD 1-2 Category B Mild — moderate COPD with a low risk of exacerbations & more symptoms. 50% ≤ FEV₁ < 80% predicted	Or LABA	E.g. glycopyrronium 44 μg once daily (Seebri®) E.g. indacaterol 150 μg once daily (Onbrez® Breezehaler), salmeterol 50 μg BD (Serevent® Diskus)		LAMA + LABA
GOLD 3-4 Category C Moderate—severe COPD with a high risk of exacerbations & less symptoms. 30% ≤ FEV₁ < 50% predicted	or LAMA	E.g. budesonide/ formoterol 320/9 µg BD (Bufomix® Easyhaler 320/9) E.g. glycopyrronium 44 µg once daily (Seebri®)		LAMA + LABA or LAMA + PDE-4 inhibitor (i.e. roflumilast - not reimbursed) or LABA + PDE-4 inhibitor
GOLD 3-4 Category D Moderate-severe COPD with a high risk of exacerbations & more symptoms. FEV1 < 30%	and/or	E.g. budesonide/ formoterol 320/9 µg BD (Bufomix® Easyhaler 320/9		ICS + LABA + LAMA or ICS + LABA + PDE-4 inhibitor or LAMA + LABA or LAMA + PDE-4 inhibitor
predicted	and the same	E.g. glycopyrronium 44 μg		LAIVIA + PDE-4 IIIIIIDILOF

once daily (Seebri®)

predicted

Practice Points – Management of COPD

- Regular treatment with long-acting inhaled bronchodilators is more effective and convenient than treatment with short-acting bronchodilators.
- Combination bronchodilator therapy (long-acting beta, agonist + longacting muscarinic agonist [LABA + LAMA]) may increase the degree of bronchodilatation with fewer associated side effects.
- Inhaled corticosteroid (ICS) monotherapy is not recommended in the longterm treatment of COPD, however, combinations containing a LABA and ICS may be appropriate in patients at high risk of exacerbations. ICS use is associated with a higher risk of pneumonia.
- A patient's ability to use an inhaler correctly is crucial when prescribing an inhaler device:
 - ✓ Dry powder inhalers (DPIs) may be preferred in COPD as the particle deposition tends to be more central with the fixed airflow limitation and lower inspiratory flow rates in COPD.
 - Some COPD patients may have difficulty using a DPI, which often involves loading the dose, and a pressurised metered dose inhaler (pMDI), breath-actuated MDI or soft mist inhaler may be considered. A spacer device, e.g. Volumatic®, may be useful when coordinating actuation and inhalation is a problem.
- Nebulised bronchodilator therapy may be necessary where patients are unable to ambulate or during exacerbations. There is a limited role, however, for nebulised corticosteroids in the management of chronic COPD and during exacerbations. Use of nebulised corticosteroids is associated with an increased risk of non-fatal pneumonia and prescribers should exercise due caution.

Inhalers for the Treatment of COPD – Summary of Costs



Drug and device	Cost per device €	Cost per actuation €	Cost per day €
Short-acting beta ₂ agonists (SABA)			
Salbutamol (100 micrograms)			
Gerivent® CFC-free (pMDI)	2.95	0.015	0.12
Salamol® (pMDI)	2.96	0.015	0.12
Salbul® (pMDI)	3.01	0.015	0.12
Ventolin® Evohaler (pMDI)	3.10	0.015	0.12
Salamol® Easi-breathe (BA MDI)	7.95	0.039	0.31
Novolizer® Salbutamol (DPI)	8.90	0.045	0.36
Terbutaline (500 micrograms)			
Bricanyl® Turbohaler (DPI)	6.10	0.061	0.24
Short-acting muscarinic antagonist	s (SAMA)		
Ipratropium (20 micrograms)			
Atrovent® (pMDI)	2.67	0.013	0.10
Long-acting beta ₂ agonists (LABA)			
Formoterol (various strengths)			
Foradil® Aerolizer 12 μg (DPI)	24.03	0.40	0.80
Oxis® Turbohaler 12 μg (DPI)	25.32	0.42	0.84
Oxis® Turbohaler 6 μg (DPI)	20.16	0.34	1.36
Indacaterol (various strengths)			
Onbrez® Breezehaler 150 μg			
(DPI)	32.18	1.07	1.07
Onbrez® Breezehaler 300 μg			
(DPI)	34.91	1.16	1.16
Salmeterol (various strengths)			
Serevent® 25 μg Evohaler (pMDI)	29.72	0.24	0.96
Serevent® 50 μg Diskus (DPI)	29.76	0.48	0.96

Drug and device	Cost per device €	Cost per actuation €	Cost per day €
Long-acting muscarinic antagonists (L	AMA)		
Aclidinium bromide (322 micrograms)			
Elkira Genuair®	37.26	0.62	1.24
Glycopyrronium (44 micrograms)			
Seebri [®]	37.26	1.24	1.24
Tiotropium (various strengths)			
Spiriva® Handihaler 18 μg	40.40	1.35	1.35
Spiriva [®] Respimat 2.5 μg	43.44	0.72	1.44
Combined long-acting beta ₂ agonist/lo	ong-acting mu	iscarinic antagon	ist
Indacaterol/Glycopyrronium (85 micro	ograms/43 mi	crograms)	
Ultibro® Breezehaler (DPI)	55.08	1.84	1.84
Inhaled corticosteroids (ICS) [ICS monother	erapy not indicated	in long-term manageme	ent of COPD]
Budesonide (400 micrograms) Pulmicort® Turbohaler (DPI)	14.73	0.295	0.60
Fluticasone (various strengths)			
Flixotide® Diskus (DPI) 500 μg	34.40	0.573	1.15
Flixotide® Evohaler (pMDI) 250 μg	22.82	0.38	1.52
Combined inhaled corticosteroid/long	g-acting beta ₂	agonist (various	strengths)
Budesonide/Formoterol (micrograms)			
Bufomix® Easyhaler 320/9 (DPI)	31.86	0.53	1.06
Symbicort® 400/12 (DPI)	47.66	0.790	1.59
Fluticasone/Salmeterol (micrograms)			
Seretide® 500/50 Diskus (DPI)	53.70	0.895	1.79
Fluticasone/Vilanterol (micrograms)			
Relvar® Ellipta 92/22 (DPI)	39.47	1.32	1.32

Costs listed reflect the **reimbursed price**. Private patients pay significantly more than the reimbursed price.

BA MDI – Breath-actuated metered dose inhaler pMDI – Pressurised metered dose inhaler DPI – Dry powder inhaler μg = microgram Medicines Management Programme. Version 1.0, July 2014



Management of Asthma in Clinical Practice



Each patient should start therapy at the step most appropriate to his/her symptoms and move up and down the treatment ladder according to symptoms.

Review treatment every 3 months; if control has been achieved, a stepwise reduction may be possible (Section 4.3 of Prescribing and Cost Guidance - Asthma).

Step 1

Inhaled short-acting beta₂ agonist (SABA) as required.

Mild intermittent asthma

Step 2

Add inhaled corticosteroid (ICS). Titrate dose to severity of disease.

Regular controller therapy

Step 3

Add long-acting beta₂ agonist (LABA) or increase ICS.

Initial add-on therapy

Step 4

Consider increasing ICS to maximum dose with LABA. Stop LABA if no benefit.

Persistent poor control

Step 5

High dose ICS ± daily low dose oral corticosteroid. Theophylline. (Specialist care).

Continuous/ frequent use of corticosteroids

Increasing severity of disease



Practice points

- Where a patient requires two puffs of SABA twice weekly, a regular ICS is indicated
- A patient's ability to use an inhaler correctly is a crucial consideration when prescribing an inhaler device.
 - Most patients can be taught to use a pressurised metered dose inhaler (pMDI), the least expensive and therefore, preferred device. Where a patient has difficulty using a pMDI, a spacer device or a breath-actuated MDI may be useful.
 - Pry powder inhalers (DPIs) are useful for those unable to use a pMDI. However, inspiratory flow rate must be sufficient to enable lung deposition, therefore, DPIs may be less suitable for elderly patients or those experiencing an acute exacerbation
- Patients must be trained on how to use their device; inhaler technique should be assessed regularly.
- It is good practice to use one inhaler device type per patient, i.e. a pMDI or DPI for both reliever and maintenance therapy. This avoids the need to train the patient in more than one device type and reduces confusion. Having more than one device type in use or switching between devices can lead to incorrect dosing, adverse effects and drug wastage.
- Seretide® Diskus should never be prescribed at a dose of two puffs twice daily; the correct dose is one puff twice daily.

Inhalers for the Treatment of Asthma – Summary of Costs



Drug and device	Cost per device €	Cost per actuation €	Cost per day €	
Short-acting beta ₂ agonists (SABA)				
Salbutamol (100 micrograms)				
Gerivent® CFC-free inhaler (pMDI)	2.95	0.015	0.06	
Ventamol® CFC-free inhaler (pMDI)	2.95	0.015	0.06	
Salamol® CFC-free inhaler (pMDI)	2.96	0.015	0.06	
Salbul® (pMDI)	3.01	0.015	0.06	
Ventolin® Evohaler (pMDI)	3.10	0.015	0.06	
Salamol® Easi-breathe (BA MDI)	7.95	0.040	0.16	
Novolizer® Salbutamol (BA DPI)	8.90	0.045	0.18	
Ventolin® Diskus (DPI)	4.48	0.075	0.30	
Terbutaline (500 micrograms)		<u>'</u>		
Bricanyl® Turbohaler (DPI)	6.10	0.06	0.24	
Short-acting muscarinic antagonis	ts (SAMA)			
Ipratropium (20 micrograms)				
Atrovent® (pMDI)	2.67	0.013	0.05	
Inhaled corticosteroids (ICS)				
Beclometasone (micrograms)				
Beclazone® 50 CFC-free (pMDI)	5.36	0.027	0.05	
Beclazone® 50 Easi-breathe (BA MDI)	5.58	0.028	0.06	
Becotide® 50 Evohaler (pMDI)	6.07	0.030	0.06	
Qvar® 50 aerosol (pMDI)	10.86	0.054	0.11	
Beclazone® 100 CFC-free (pMDI)	10.45	0.052	0.10	
Beclazone® 100 Easi-breathe (BA MDI)	10.86	0.054	0.11	
Becotide® 100 Evohaler (pMDI)	12.18	0.061	0.12	
Qvar® 100 aerosol (pMDI)	23.24	0.116	0.23	
Beclazone® 200 CFC-free (BA MDI)	21.09	0.105	0.21	
Beclazone®200 Easi-breathe (BA MDI)	21.09	0.105	0.21	
Beclazone® 250 CFC-free(pMDI)	22.35	0.112	0.22	
Beclazone® 250 Easi-breathe (BA MDI)	23.24	0.116	0.23	
Becotide® 250 Evohaler (pMDI)	25.24	0.126	0.25	
Budesonide (micrograms)				
Pulmicort® 100 Turbohaler (DPI)	17.24	0.086	0.17	
Pulmicort® 200 Turbohaler (DPI)	14.77	0.148	0.30	
Novolizer® 200 Budesonide (DPI)	20.00	0.20	0.40	
Pulmicort® 400 Turbohaler (DPI)	14.73	0.295	0.60	
Novolizer® 400 Budesonide (DPI)	20.00	0.40	0.80	
Fluticasone (micrograms)				
Flixotide® 50 Evohaler (pMDI)	8.85	0.074	0.15	
Flixotide® 50 Diskus (DPI)	6.10	0.102	0.20	

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Drug and device (continu	ed)	Cost per	Cost per actuation	Cost per
Strength of combination preparation		device €	€	day €
Flixotide® 100 Diskus (DPI)		9.72	0.162	0.32
Flixotide® 125 Evohaler (pMDI)		13.42	0.224	0.45
Flixotide® 250 Evohaler (pMDI)		17.99	0.30	0.60
Flixotide® 250 Diskus (DPI)		20.08	0.335	0.67
Flixotide® 500 Diskus (DPI)		34.40	0.573	1.15
Long-acting beta ₂ agonists (LA	BA) (No r	role for LABA	monotherapy in a	asthma)
Formoterol				
Oxis® Turbohaler 6 micrograms (DPI)		20.16	0.34	0.68
Oxis® Turbohaler 12 micrograms (DPI))	23.97	0.40	0.80
Foradil® Aerolizer 12 micrograms (DP)	24.03	0.40	0.80
Salmeterol (micrograms)				
Salmeterol Neolab® 25 (pMDI)		26.37	0.22	0.44
Serevent® Evohaler 25 (pMDI)		28.72	0.24	0.48
Serevent® Diskus 50 (DPI)		28.76	0.48	0.96
Combined inhaled corticostero	oid (ICS) 8	& long-acting	beta2 agonist (LA	BA)
Budesonide/Formoterol (microgra	ams) [cost,	/day represents	maintenance treatme	nt only]
Symbicort® Turbohaler 100/6 (DPI)	Lower	42.17	0.35	0.70
Bufomix® Easyhaler 160/4.5	Medium	31.86	0.26	0.53
Symbicort® Turbohaler 200/6 (DPI)	strength	48.61	0.41	0.82
Bufomix® Easyhaler 320/9	Higher	31.86	0.53	1.06
Symbicort® Turbohaler 400/12 (DPI)	strength	47.66	0.79	1.58
Fluticasone/Formoterol (microgra	ıms)			
Flutiform® 50/5 (pMDI)	Low	27.00	0.23	0.46
Flutiform® 125/5 (pMDI)	Medium	39.96	0.33	0.66
Flutiform® 250/10 (pMDI)	Higher	55.08	0.46	0.92
Fluticasone/Salmeterol (microgra	ms)			
Seretide® 50/25 Evohaler (pMDI)		29.12	0.24	0.48
Seretide® 125/25 Evohaler (pMDI)	Lower	43.18	0.36	0.72
Seretide® 100/50 Diskus (DPI)	strength	31.42	0.52	1.04
Seretide® 250/25 Evohaler (pMDI)	Medium	57.84	0.48	0.96
Seretide® 250/50 Diskus (DPI)	strength	40.96	0.68	1.36
Seretide® 500/50 Diskus (DPI)	Higher	53.55	0.89	1.78
Fluticasone/Vilanterol (microgran	ns)			
Relvar® Ellipta 92/22 (DPI)	Medium	39.47	1.32	1.32
Relvar® Ellipta 184/22 (DPI)	Higher	52.43	1.75	1.75

BA MDI – Breath-actuated metered dose inhaler; **pMDI** – Pressurised metered dose inhaler **DPI** – Dry powder inhaler.