RACGP
Royal Australian College of General Practitioners

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20 April 2023

Professor Andrew Wilson
Pharmaceutical Benefits Advisory Committee (PBAC)
Via email: pbac@health.gov.au

Cc: Ms Penny Shakespeare, Deputy Secretary Health Resourcing
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Ms Adriana Platona, First Assistant Secretary Technology Assessment & Access
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Mr Nikolai Tsyganov, Assistant Secretary Pricing and PBS Policy Branch
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Dear Professor Wilson,

RE: Advised listing change for Fluticasone Propionate 50 microgram

I am writing regarding the 1 April 2023 changes by PBAC to the General Schedule (Section 85) listing, population criteria and treatment criteria for fluticasone propionate 50 microgram/actuation inhalation, 120 actuations indicated for the prophylactic management of asthma.

The RACGP was not aware of any open consultation on this issue before the changes were announced. The RACGP is very concerned that these changes have implications in equity of access, clinical risk in delaying initiation of this medication, significant health and/or mortality risk from substitution with other medicines and broader costs to the health system of otherwise unnecessary consultations with paediatric respiratory physicians and paediatricians. I specifically highlight the impact of this change on general practitioners (GPs) and their patients by:

- Restricting to patients aged under six years
- Amending to an Authority Required (telephone or electronic)
- Requiring initiation by a respiratory physician or a paediatrician.

The Australian Asthma Handbook recommends that "an inhaled corticosteroid should be considered as the first choice preventer for those (children) with symptoms that are frequent (e.g. daytime or night-time symptoms at least once per week), symptoms that restrict activity or sleep, or a history of severe flare-ups (e.g. requiring treatment in the emergency department or hospital admission)."[1] Fluticasone propionate 50 microgram (FP 50 mcg) has been the mainstay of asthma management for children and adolescents for decades. The RACGP is unaware of any inappropriate prescribing of fluticasone propionate in young children, and in the absence of reasonable alternatives that are equally as effective, safe and accessible, the clinical need for this change is unclear. Australian Asthma Guidelines do not require all young children to be diagnosed with asthma by a respiratory physician or a paediatrician. In fact, GPs see most children under 5 years of age with wheeze/asthma.

As a result of the PBAC changes, when a GP determines a child with asthma aged between 1-5 years should be initiated on inhaled corticosteroids (ICS), the GP has three options available:

1. Refer to a paediatrician or respiratory physician.
2. Prescribe FP 50mcg on a private script.
3. Prescribe other medicines 'off label' which will often involve higher-dose steroids.

The majority (85.3%) of paediatrician clinicians and clinician physicians (89.9%) are in a major city or a location considered as MMM1.[2,3] Accessing these clinicians will be challenging for patients in rural and remote locations. Access to affordable medication is very important for socioeconomically vulnerable populations such as Aboriginal and Torres Strait Islander peoples and other populations in need of more asthma care. Poverty has been associated with increased risk of asthma exacerbation in children.[4] There are also families who have multiple children and parents with asthma (and other conditions). Inability to access PBS subsidies plus the cost of the script being ineligible to count towards the safety net, places these groups at a significant disadvantage. These groups will also incur the additional cost of paediatrician or respiratory physician appointments. At the cost of $11 to $28 per inhaler on a private script, and a lack of access to bulk-billing non-GP specialists, this will be a significant imposition for families who rely on concessions or safety nets.

Request to PBAC

1. Remove the requirement for a paediatrician or respiratory physician to initiate FP 50 mcg for children 1-5 years and reinstate GP PBS prescribing rights.
2. Continue access to PBS-subsidised FP 50 mcg for children 6 years and older.
3. Remove the Authority Required, or if it cannot be removed entirely, change to Authority Streamlined.

Further information in support of our requests is provided in Appendix 1.

The RACGP seeks clarification if this was a funding-based decision, or a decision based on a new interpretation of published evidence. We would welcome the opportunity to discuss this matter further to better understand how these decisions are made and identify ways to ensure safety and minimise impact on consumers. Please contact Mr Stephan Groombridge, Acting Chief Policy Officer on (03) 8699 0544 or via stephan.groombridge@racgp.org.au if you have any questions or comments regarding this letter.

Yours sincerely,

Dr Nicole Higgins
President

Cc RACGP Respiratory Specific Interest Group Chair, Dr Kerry Hancock

Appendix 1

Restricting to patients aged under six years

If children aged 6 years of age and older have had their asthma controlled on FP 50 mcg, they should be able to continue to access this medicine on the PBS. Forcing a change from FP 50 mcg can result in:

- Transferring to higher doses or alternate ICS which has potential adverse outcomes including impact on growth.[5] There is some evidence that the effect of fluticasone on children's growth may be less.[6]
- Switching to beclomethasone which may also result in worse asthma control given the ICS dose potencies are not the same.[7]
- Potential harms from over-reliance on short-acting beta agonists (SABA), overuse of oral corticosteroids (OCS) and higher ICS doses.
- Potential confusion for the patient, their parent or carer when being required to switch to a different ICS at 6 years of age.

Amending to an Authority Required and requiring initiation by a respiratory physician or a paediatrician.

The current Asthma guidelines for Australia[8] and internationally[9] recommend the need to commence a preventer in children aged 1-5 years if they have respiratory symptoms in between viral infections, as do the Therapeutic Guidelines. Additionally, a preventer medication (such as montelukast or an ICS) is indicated if the child has had a moderate-severe flare up requiring OCS.

Currently, FP 50 mcg is the only ICS licensed for use in the 1-5 years age group according to the Australian Register for Therapeutic Goods (ARTG). Additionally, there are studies that indicate that ICS may be preferrable to montelukast for some patients aged 1-5 years.[10,11,12,13] The Budesonide Turbuhaler has no age restrictions on the ARTG, but it is problematic to use correctly in young children.

The recommended dose of fluticasone propionate is "50 to 100 micrograms twice daily" for children 1 year and older, according to the Australian Asthma Handbook and the Product Information brochure. This exact dosage is only possible with FP 50mcg.

GPs see most children under 6 years of age with wheeze or asthma. Therefore, a large proportion of patients in this group have had their FP 50 mcg initiated by a GP.

The RACGP is concerned that by making FP 50 mcg an Authority Required prescription and requiring initiation of FP 50 mcg by a respiratory physician or paediatrician, there is a risk that:

- children aged 1-5 years will be undertreated or have uncontrolled asthma. This effect is likely to be exacerbated in rural and regional areas where access to paediatricians and respiratory specialists is more challenging.

- children aged 1-5 years, who have been well controlled on FP 50 mcg, will be swapped to fluticasone propionate 125 microgram (FP 125 mcg) to avoid the burden of the new Authority requirements. For example, FP 50mcg twice a day converted to FP 125mcg once daily and FP 50mcg x 2 puffs twice a day to FP 125mcg twice a day. Children will end up on higher ICS doses for the sake of convenience and lower costs and some will be changed to other ICS formulations such as ciclesonide 80 mcg once daily.
- patients may rely on SABA and OCS to control asthma symptoms. Overuse of these drugs is associated with death caused by asthma. Over-reliance on SABA and suboptimal use of ICS is associated with risk of asthma exacerbation in children.[14] SABA overuse is associated with an increased risk of asthma mortality.[15] The Global Initiative on Asthma (GINA) 2019 and 2020 updates acknowledged the risks associated with SABA overuse and the tendency of patients to underuse ICS and overuse SABA. International Guidelines (including the Australian Asthma Handbook) advise reducing the exposure to these drugs. There are significant long-term risks associated with OCS especially the cumulative dose.[16,17] Concession card holders will be able to access SABA at a lower cost than FP 50 mcg which could contribute to overuse.
- it creates a false assumption that GPs are unable to diagnose and prescribe appropriately for children with asthma aged between 1 and 5 years. This could further result in many more referrals to paediatricians as GPs take a more cautious approach to childhood asthma, delaying appropriate medication whilst awaiting a potentially unnecessary paediatrician review. It may also erode the community trust in GPs due to obligatory referrals to paediatricians and respiratory physicians.
- it further erodes peoples' confidence in the safety of ICS, suggesting they are unsafe or need monitoring.
- it potentially undermines all the asthma education and upskilling to GPs that has occurred over the last few years.

The RACGP is also concerned about the added expense for patients and the health system by the requirement for a respiratory physician or paediatrician to initiate this medicine. There are downstream effects including delaying specialist visits for other serious respiratory problems in young children or delayed review by paediatricians for non-respiratory related conditions.

In many parts of Australia there are very few bulk-billing paediatricians and respiratory physicians and lengthy waitlists which mean that patient access will be restricted, particularly for vulnerable groups. Patient accessibility to non-GP specialists is exacerbated in rural and remote regions, with waiting times often exceeding 12 months.

There is a specific issue for Aboriginal and Torres Strait Islander people, who have access to the Closing the Gap PBS co-payment. There is precedent for some medications only being available on the PBS for Aboriginal and Torres Strait Islander people. Whilst there is not a predisposition for asthma among children who are Aboriginal or Torres Strait Islander, there is a need for special consideration of this group because being Aboriginal or Torres Strait Islander is associated with much

reduced income, and much reduced access to non-GP specialists (either due to cost or geography or both). This would be a partial solution at best and RACGP's preference is for a complete reversal of the PBAC changes to FP 50mcg.

The RACGP is calling for GPs to continue to have the right to prescribe this important preventer medicine for children aged 1 to 5, and for this medicine to continue to be available beyond 5 years of age.

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