NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

15 November 2013

Approval of proposal relating to the listing of montelukast (Singulair)

PHARMAC is pleased to announce the approval of an agreement with Merck Sharp and Dohme (New Zealand) Ltd relating to the supply of montelukast (Singulair) for the treatment of pre-school wheeze, exercise-induced asthma and aspirin desensitisation from 1 December 2013.

This was the subject of a consultation letter dated 11 October 2013. In summary, the effect of the decision will result in:

- A reduction in the net price paid for Singulair from 1 December 2013;
- Subsidy and delisting protection for Singulair until 31 December 2016; and
- A change in the Special Authority criteria relating to use for pre-school wheeze and exercise induced asthma.

Details of the proposal

- The price and subsidy of Singulair listed in Section B (Community) and Section H (Hospital) of the Pharmaceutical Schedule will remain the same, as follows:

Chemical	Presentation	Brand	Pack size	Price and subsidy (ex-man., ex. GST)
Montelukast	Tab	Singulair	28 x 4 mg	$18.48
Montelukast	Tab	Singulair	28 x 5 mg	$18.48
Montelukast	Tab	Singulair	28 x 10 mg	$18.48

- From 1 December 2013, changes to the Special Authority criteria and restrictions that apply to montelukast will be as follows (additions in bold, deletions in strike through):

Initial application (Pre-school wheeze) from any relevant practitioner. Approvals valid for one year for applications meeting the following criteria:

~~All of the following~~ **Both:**

1 To be used for the treatment of intermittent severe wheezing (possibly viral) ~~in children under 5 years~~; and

2 ~~The patient has trialled inhaled corticosteroids at a dose of up to 400µg per day beclomethasone or budesonide, or 200 µg per day fluticasone for at least one month; and~~

3 The patient ~~continues to have~~ **has had** at least three episodes in the previous 12 months of acute wheeze severe enough to seek medical attention. ~~severe exacerbations at least one of which required hospitalisation defined as in patient stay or prolonged Emergency Department treatment) in the past 12 months.~~

Renewal (pre-school wheeze) - only from a relevant practitioner. Approvals valid for two years where the treatment remains appropriate and the patient is benefitting from treatment.

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Initial application (exercise-induced asthma) from any relevant practitioner. Approvals valid without further renewal, unless notified, for applications meeting the following criteria:

All of the following:

1 Patient ~~is being treated~~ **has been trialed** with maximal asthma therapy, including inhaled corticosteroids and long-acting beta-adrenoceptor agonists; and

2 Patient continues to receive optimal inhaled corticosteroid therapy; and

3 Patient continues to experience frequent episodes of exercise-induced bronchoconstriction.

Initial application (aspirin desensitisation) only from a clinical immunologist or allergist. Approvals valid for one year, for applications meeting the following criteria:

All of the following:

1. Patient is undergoing aspirin desensitisation therapy under the supervision of a clinical immunologist or allergist; and
2. Patient has moderate to severe aspirin-exacerbated respiratory disease or Samter's triad; and
3. Nasal polyposis, confirmed radiologically or surgically; and
4. Documented aspirin or NSAID allergy confirmed by aspirin challenge or a clinical history of severe reaction to aspirin or NSAID where challenge would be considered dangerous

- Singulair will have protection from subsidy reduction and delisting until 31 December 2016;

- A rebate, reducing the net price of the product from 1 December 2013, will apply to Singulair.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 25 October 2013 were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal, and the following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
A clinician commented that the changes to Special Authority criteria for preschool wheeze would open up the use of this drug to any asthmatic and not just to children with recurrent wheeze and that that posed significant fiscal risk.	The initial criteria for treatment stipulates that it is for preschool wheeze and the criteria includes the wording “treatment of intermittent severe wheezing”.
A clinician responded that the proposed criteria changes are more sensible than current criteria and commented that it meets the gap in the market for recurrent viral wheeze without interval symptoms, for whom inhaled corticosteroids are ineffective.	PHARMAC noted the response.
The New Zealand Medical Association supported the proposal to ease the criteria for montelukast, commenting that it would lead to better care of patients with asthma.	PHARMAC noted the response.

Theme	Comment
A supplier responded that it was planning to submit a tender bid at a lower price per pack for sole supply and questioned if there were clinical reasons giving MSD preference?	We note that consultation is not an invitation for counterproposals, and it is important for PHARMAC to maintain a degree of integrity with suppliers such that negotiations are not turned over during consultation because of last minute offers of a better deal. This proposal does not offer sole supply status and other suppliers of montelukast are welcome to seek a listing.

More information

If you have any questions about this decision, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.