POST-MARKET REVIEW OF AUTHORITY REQUIRED PBS LISTINGS

Contents

Pulmonary Hypertension Society of Australia and New Zealand Inc.
PO BOX 133, Sans Souci, NSW
ABN 11407595406
30-sept.-14

Pulmonary Hypertension society of Australia and New Zealand Inc.

The PHSANZ Inc. is pleased to have the opportunity to provide a submission to the current post-market review of authority required PBS listings.

The Pulmonary Hypertensions Society of Australian and New Zealand (PHSANZ) Inc. is a not for profit scientific representing specialists physicians and allied healthcare workers across Australia and New Zealand who care for patients with pulmonary hypertension. The PHSANZ has an overarching mission to advocate for a sustainable 'model of care' that leads to equitable and timely access to skilled clinicians in the diagnosis, treatment and ongoing management of patients with Pulmonary Hypertension in Australia and New Zealand. Our membership is derived primarily from clinicians within Respiratory Medicine, Cardiology, Rheumatology, physiotherapy and Nursing.

The primary objectives of the PHSANZ are:

1. To advocate for Equitable and timely access to an accurate diagnosis [1]
2. To achieve equitable and appropriate access to therapies based on international guidelines[2, 3]
3. To provide careful assessment of responses to therapies via a bi National PHSANZ pulmonary hypertension registry[4]
4. To provide a platform for future research
5. Promotion of awareness of breathlessness [5], scientific understanding and continued improvement of clinical practice

Until recently, pulmonary hypertension has been classified as a relatively rare disease [5, 6], however is placing significant burdens on our healthcare system, of which we believe may increase.

Pulmonary Hypertension Society of Australia and New Zealand Inc.
PO BOX 133, Sans Souci, NSW
ABN 11407595406

About Pulmonary Hypertension

PHT is a physiological phenomenon of elevated pulmonary blood pressure (mean PAP>25mmHg). The present aetiology includes >45 known diseases spread across 5 classification groups (Group 1-5). [2, 7]. According to the Nice 2013 world expert criteria, it is commonly associated with heart disease (Group 2) and Lung disease (Group 3) but the rarer Pulmonary Arterial Hypertension (Group 1) and Chronic Thromboembolic Pulmonary Hypertension (CTEPH) is now critically important to diagnose and treat due to recent advances in mortality outcomes from effective treatments [8, 9]. Theses patient now have a significantly improved outcome compared to their counterparts with other forms of PHT of whom treatment is still lacking. These treatments include several available drug therapies as well as Lung (or heart lung) Transplantation.

Authority required PBS listings

Pharmaceuticals Benefits Scheme (PBS) section 100 authority drugs available for the treatment of PAH commenced with Bosentan in April, 2004. Since then, a number of other agents have been made available and funded through the PBS; Iloprost- inhaled, Sildenafil (oral), Epoprostenol (IVI), Sitaxentan (oral-now withdrawn), Abrisentan (oral), Tildalafil (oral), Macetentan (oral) and Riogiguat (oral) have been approved and funded by the PBS. These medicines cover the three main pathways thought important to pulmonary hypertension pathogenesis; Endothelin; Nitric oxide/cGMP and Prostaglandin. [10, 11]

The section 100 listing of the above mentioned therapies has accompanied strictly limited prescribers (at designated centres), mandatory initial investigation, mandatory reinvestigation and reapplication for continuation or therapy / reapplication for change of therapy.

The required initial investigations are not out of step with reasonable clinical practice. The repeated applications however, to continue medications were initially link to a requirement to track patient outcomes [12]. This tracking of outcomes no longer exists and this important review process has been taken up (without any government funding) by the PHSANZ who now run a registry across ANZ. We believe this aspect may be able to be streamlined. Further, PBS will reimburse only one drug at a time and therefore it may be required to “switch” between therapies in order to try for a better outcome in those patients deteriorating on therapy a to therapy b that has a different mode of action therapeutically.

Pulmonary Hypertension Society of Australia and New Zealand Inc.
PO BOX 133, Sans Souci, NSW
ABN 11407595406
30-sept.-14

High burden on prescribers

All pulmonary hypertensions therapies require section 100 authority approvals for PBS subsidy. Currently, written applications need to be sent by post to Medicare in Hobart which processes the application and then mails the approved script to the patient or prescriber. Written applications are required to initiate, change and continue medication. The time required to commence and maintain patients on therapy is substantial. We would estimate 0.4 EFT PHT nurse time and 0.2 EFT administrative time per 100 patients simply to comply with the PBS requirements for initial and ongoing provision of therapy. Thus across Australia, a large amount of skilled clinical staff are tied up with these reporting requirements. The implication of having skilled staff tied up with regulatory burdens is substantial and has undeniably impacts on patient's access to timely and equitable services. There is usually also a delay of 2 -3 weeks to commence treatment because of the need to post application off for approval. This delay in timely access to medications may impact survival.

Recommendation

We believe that careful initial assessment and diagnosis is critical to getting the right patients on the right drug (including Echocardiography, right heart catheterisation and 6 minute walk). Switching within a class (usually related to toxicity concerns), as well as continuation of the same drug should be allowed by simple repeat authority prescription without the need for reapplication. Swapping to another class of drug should require re-evaluation (Echo RHC and 6MWT) and submission of application. As recommended in international guidelines at least 6 month clinical review assessing functional class, 6MWT distance as well as echocardiogram should continue but the results can be directly entered into the PHSANZ data base as part of our PHSANZ registry follow up programme. The PHSANZ registry could if appropriately resourced, potentially report data directly to the PBS, as we have incorporated all forms within the system and could provide email reporting submission directly from our database.

Pulmonary Hypertension Society of Australia and New Zealand Inc.
PO BOX 133, Sans Souci, NSW
ABN 11407595406

Summary recommendation

1. Initial assesment and commencement of a section 100 authority PBS theraputic for PAH should remain as is, although any streamlining or electronic modifications would be valauable.
2. Commencement and switching to different drug class after the initial PBS therpay has been intiated requires detailed section 100 submission as occurs presently. This may be modified and have this aspect as part of a repoting system provided (if funded) to the PBS on a six monthly / yearly basis.
3. All repeat prescription beyond the first 6 month requires only authority (? Streamline authority).
4. The PHSANZ may be able to "partener" with the PBS to provide detailed reports / practice audits that would eliminate timely and burdensome paperwork from both the PBS and the clinical staff across Australia. With appropriate resourcing,we would be happy to facilitate a pilot program to this effect.

Yours sincerely,

Professor Trevor Williams
PHSANZ | President
PHSANZ | Scientific Chair
Monash University
Clinical Director, Allergy, immunology and Respiratory Medicine,
The Alfred Hospital, Melbourne, VIC

Assoc. Professor Geoff Strange
PHSANZ | CEO
University of Notre Dame
Dept. of Cardiology,
Royal Prince Alfred Hospital, Sydney, NSW

Pulmonary Hypertension Society of Australia and New Zealand Inc.
PO BOX 133, Sans Souci, NSW
ABN 11407595406
30-sept.-14

References

1. Strange G, Gabbay E, Kermeen F, Williams T, Carrington M, et al. 2013. *Pulm Circ* 3: 89-94
2. Galie N, Corris PA, Frost A, Girgis RE, Granton J, et al. 2013. *J Am Coll Cardiol* 62: D60-72
3. Hoeper MM, Bogaard HJ, Condliffe R, Frantz R, Khanna D, et al. 2013. *J Am Coll Cardiol* 62: D42-50
4. McLaughlin VV, Gaine SP, Howard LS, Leuchte HH, Mathier MA, et al. 2013. *J Am Coll Cardiol* 62: D73-81
5. Strange G, Williams T, Kermeen F, Whyte K, Keogh A. 2014. *Intern Med J* 44: 114-23
6. Strange G, Playford D, Stewart S, Deague JA, Nelson H, et al. 2012. *Heart* 98: 1805-11
7. Simonneau G, Gatzoulis MA, Adatia I, Celermajer D, Denton C, et al. 2013. *J Am Coll Cardiol* 62: D34-41
8. McLaughlin VV, Langer A, Tan M, Clements PJ, Oudiz RJ, et al. 2013. *Chest* 143: 324-32
9. Ghofrani HA, D'Armini AM, Grimminger F, Hoeper MM, Jansa P, et al. 2013. *N Engl J Med* 369: 319-29
10. Tuder RM, Stacher E, Robinson J, Kumar R, Graham BB. 2013. *Clin Chest Med* 34: 639-50
5. 11. Tuder RM, Archer SL, Dorfmuller P, Erzurum SC, Guignabert C, et al. 2013. *J Am Coll Cardiol* 62: D4-12
6. 12. Keogh A, Strange G, McNeil K, Williams TJ, Gabbay E, et al. 2011. *Intern Med J* 41: 227-34

Pulmonary Hypertension Society of Australia and New Zealand Inc.
PO BOX 133, Sans Souci, NSW
ABN 11407595406
30-sept.-14