Varenicline: Amendments to Special Authority funding

Varenicline is funded under Special Authority for people who:

1. Are enrolled, or about to enrol, in a smoking cessation programme with a prescriber or nurse monitoring; and
2. Have tried, but failed, to quit on at least two separate occasions using nicotine replacement therapy (NRT) with at least one of these attempts involving a comprehensive cessation programme; or
3. Have tried previously to quit using buproprion or nortriptyline; and
4. Have not used funded varenicline in the last 12 months; and
5. Are not pregnant

Additionally, recent amendments to Special Authority funding have been made in order to clarify that:

- Varenicline will not be funded Close Control in amounts less than two weeks
- The maximum funded quantity of varenicline is 12 weeks' worth of treatment (including the "starter pack")

It is recommended that patients be reminded that they are only eligible to receive funding for one 12 week course of varenicline treatment every 12 months.

How to make sure the 12 week course is completed

Varenicline treatment begins one to two weeks before an agreed "quit-date", with a two week "starter-pack", during which time the dose increases, followed by a ten week maintenance regimen as shown following:

Dose	Duration
0.5 mg once daily	First three days
0.5 mg twice daily	Next four days
1 mg twice daily	Next seven days until starter pack finished
1 mg twice daily	Ten weeks

To help ensure that patients receive the full funded 12 week course, both the starter pack and the ten weeks of maintenance treatment should be included on the same prescription.

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Rx **HFA** **12 Jul 2011**

Dispense stat list medicines once only unless endorsed close control

Varenicline Starter Pack Tab
Sig: Begin 1–2 weeks before quitting 0.5 mg once daily on days 1–3, 0.5 mg twice daily on days 4–7 then 1 mg twice daily thereafter
Mitte: 2 weeks

Varenicline 1mg Tab
Sig: 1 mg twice daily
Mitte: 10 weeks

A suggested strategy for general practitioner, practice nurse and pharmacist to assist with patient compliance is outlined as follows:

What can the general practitioner do?

1. Agree on a quit date with the patient and provide contact details for a smoking cessation support programme

2. Prescribe 12 weeks of varenicline (two week "starter-pack" + ten week maintenance course) on the same prescription, offer cessation support and advise on possible adverse effects
3. Follow-up phone call from practice nurse to enquire about adverse effects
4. Offer a follow-up consultation with General Practitioner or Practice Nurse if required

What can the pharmacist do?

1. Dispense two week "starter pack" plus two weeks maintenance course with instructions and advise on adverse effects
2. Dispense four week maintenance course and offer cessation support and enquire about adverse effects
3. Dispense a final four week maintenance course and continue to offer cessation support and check for adverse effects

Who should not take varenicline?

Varenicline should not be taken with other smoking cessation medicines.

Children aged under 18 years, and women who are pregnant or breast feeding should not be prescribed varenicline.

Caution is advised in prescribing varenicline to people with renal impairment. In cases of severe impairment (estimated creatinine clearance <30 mL/min) dosing should not exceed 1 mg/day. Patients with end stage renal disease should not take varenicline.[2]

Adverse effects

Nausea is experienced in approximately 30% of patients taking varenicline, however, this generally occurs early in treatment, is mild to moderate and dissipates with time.[3]

Other adverse effects include; insomnia and abnormal dreaming, headaches and dizziness, constipation, dry mouth and general fatigue.[2] By explaining to patients that they may briefly experience some of these symptoms, the likelihood of them completing the full 12 week course is increased.

There have been several reports in New Zealand of suicidal thoughts in patients taking varenicline which were resolved once treatment ceased. Although it is important that patients are encouraged to complete their course of treatment, it is essential that patients and family are told that treatment should stop immediately, and a health professional contacted, if the patient experiences changes in behaviour, agitation or their mood becomes depressed.

Recent media coverage of a study that linked varenicline with an increased risk of cardiovascular events may have caused alarm for some people taking this medicine. The study reported by the Canadian Medical Journal looks at previous studies of varenicline that showed no increase in risk of cardiovascular effects and combines them to show a small absolute increase in risk (0.24%).[4] Medsafe is currently reviewing the safety data on varenicline, including any implications from this study. The use of varenicline has benefits and risks, and currently the benefits of using varenicline to quit smoking outweigh the risks. Smoking cessation rapidly reduces the risk of cardiovascular disease.

References

1. Cahill K, Stead LF, Lancaster T. Nicotine receptor partial agonists for smoking cessation. Cochrane Database Syst Rev 2008;3:CD006103.
2. Pfizer. Data sheet: CHAMPIX. Available from: www.medsafe.govt.nz/profs/datasheet/c/Champixtab.pdf (Accessed Jul, 2011).
3. Ministry of Health. New Zealand Smoking Cessation Guidelines 2007. Available from: www.moh.govt.nz/moh.nsf/indexmh/nz-smoking-cessation-guidelines (Accessed Jul, 2011).
4. Furberg CD, Spangler JG, Loke YK, Singh S. Risk of serious adverse cardiovascular events associated with varenicline: a systematic review and meta-analysis. CMAJ 2011 Jul 4. (Epub ahead of print).