

9 March 2009

Access widened to pegylated interferon for hepatitis B and hepatitis C genotypes 2 and 3

PHARMAC is pleased to advise that the PHARMAC Board has approved the proposal to widen funding for Roche (New Zealand) Limited's brand of pegylated interferon alpha with or without ribavirin (Pegasys) to include hepatitis B and hepatitis C genotypes 2 and 3 not yet progressed to cirrhosis. The effect of the decision is that:

- a widening of existing subsidised access to include patients with chronic hepatitis C, genotype 2 and 3 who do not have cirrhosis;
- provision of subsidies for patients with chronic hepatitis B, where patients are treatment naïve;
- restriction on the funding of the Pegatron brand of pegylated interferon alpha to existing patients (i.e. those with active approved Special Authorities); and
- delisting of Pegatron from the Pharmaceutical Schedule on completion of all existing treatment courses (i.e. at the end of the 11 month Special Authority validity period).

Details of the proposal

Pegasys, Pegasys RBV combination Pack, Roferon-A and Roferon RBV Combination Pack will all be listed in Section B of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer, excluding GST) from 1 April 2009:

Chemical	Formulation	Brand	Pack size	Price and subsidy
Pegylated interferon alpha-2A	135 µg prefilled syringe	Pegasys	1	\$362.00
	180 µg prefilled syringe		1	\$450.00
Pegylated interferon alpha-2A and ribavirin	135 µg prefilled syringe * 4 plus 112 * 200 mg ribavirin	Pegasys RBV Combination Pack	1 OP	\$1,799.68
	135 µg prefilled syringe * 4 plus 168 * 200 mg ribavirin		1 OP	\$1,975.00
	180 µg prefilled syringe * 4 plus 112 * 200 mg ribavirin		1 OP	\$2,059.84
	180 µg prefilled syringe * 4 plus 168 * 200 mg ribavirin		1 OP	\$2,190.00

Chemical	Formulation	Brand	Pack size	Price and subsidy
Interferon alpha-2a	3 m IU prefilled syringe	Roferon-A	1	\$31.32
	4.5 m IU prefilled syringe		1	\$46.98
	6 m IU prefilled syringe		1	\$62.64
	9 m IU prefilled syringe		1	\$93.96
	18 m IU multidose cartridge		1	\$187.92
	18 m IU multidose cartridge * 2 starter pack		1	\$357.84
Interferon alpha-2a with ribavirin	18 m IU multidose cartridge * 2 plus 168 * 200 mg ribavirin	Roferon RBV Combination Pack	1 OP	\$1,375,.84
	18 m IU multidose cartridge * 2 plus 168 * 200 mg ribavirin with pens and needles	Roferon RBV Combination Pack starter kit	1 OP	\$1,375,.84

For the avoidance of doubt the changes do not affect the interferon alpha-2B (Intron-A) supply status.

- A confidential rebate will apply to Pegasys, Pegasys RBV Combination Pack and Roferon RBV Combination Pack.
- Pegasys and Pegasys RBV Combination Pack will be the sole supply brand of pegylated interferon and pegylated interferon and ribavirin combination packs until 31 December 2012.
- The Special Authority restriction that applies to Pegasys and Pegasys RBV combination Pack will be replaced with the following:

Special Authority for Subsidy

PEGYLATED INTERFERON IN CHRONIC HEPATITIS C

Initial application - (genotype 1, 4, 5 or 6 infection or co-infection with HIV) from any specialist. Approvals valid for 48 weeks for applications meeting the following criteria:

1. Patient has chronic hepatitis C, genotype 1, 4, 5 or 6 infection; or
2. Patient has chronic hepatitis C and is co-infected with HIV.

Note: Consider stopping treatment if serum HCV RNA level at Week 12 remains detectable by PCR and has not reduced by at least 2 logs from the baseline level as this is predictive of treatment failure

Note: Consider reducing treatment to 24 weeks if serum HCV RNA level at Week 4 is undetectable by sensitive PCR assay (<50IU/mL) AND Baseline serum HCV RNA is <400,000IU/mL

Initial application - (genotype 2 or 3 infection without co-infection with HIV) from any specialist. Approvals valid for 6 months for applications where the patient has chronic hepatitis C, genotype 2 or 3 infection.

PEGYLATED INTERFERON IN TREATMENT-NAÏVE CHRONIC HEPATITIS B

Initial application only from a gastroenterologist, infectious disease specialist, or general physician. Approved dose is 180 mcg once weekly. Approvals valid for 48 weeks unless notified for applications meeting the following criteria:

- 1 Patient has confirmed Hepatitis B infection (HBsAg positive for more than 6 months); and
 - 2 Patient is Hepatitis B treatment-naïve; and
 - 3 ALT > 2 times Upper Limit of Normal; and
 - 4 HBV DNA < 10 log₁₀ IU/mL; and
- Any of the following:
- 4.1 HBeAg positive; or
 - 4.2 serum HBV DNA ≥ 2,000 units/ml and significant fibrosis (≥ Metavir Stage F2);
- 5 All of the following:
 - 5.1 Compensated liver disease; and
 - 5.2 No continuing alcohol abuse or intravenous drug use; and
 - 5.3 Not co-infected with HCV, HIV or HDV; and
 - 5.4 Neither ALT nor AST greater than 10 times upper limit of normal; and
 - 5.5 No history of hypersensitivity or contraindications to pegylated interferon.

Notes for Pegylated Interferon:

The recommended dose of Pegylated Interferon-alpha 2a is 180 mcg once weekly. In patients with renal insufficiency (calculated creatinine clearance less than 50ml/min), Pegylated Interferon-alpha 2a dose should be reduced to 135 mcg once weekly. In patients with neutropaenia and thrombocytopaenia, dose should be reduced in accordance with the datasheet guidelines. Pegylated Interferon-alpha 2a is not approved for use in children.

- The Special Authority restriction that applies to Pegatron will be replaced with the following:

Special Authority for Subsidy of Pegatron

Initial application - from any relevant specialist. Approvals valid for 11 months where the patient has an existing current special authority.

Note: Existing current approvals are still valid but no new applications will be accepted.

- Pegatron will be delisted from the Pharmaceutical Schedule on 1 March 2010; after all current Special Authority approvals have expired.

Feedback received

This change was the subject of a consultation letter dated 3 February 2009. We appreciate the feedback we received and acknowledge the time people took to respond. All consultation responses received by 18 February 2009 were considered in the decision on the proposed changes. Many responses were supportive of the proposal, but the following issues were raised in relation to specific aspects of the change:

Theme	Comment
Patients who fail treatment with pegylated interferon alpha-2a should still be able to access pegylated interferon alpha-2b as they currently can.	PHARMAC staff are aware that some patients have been accessing both brands in a linear treatment paradigm and note that this was never the intent of the special authority. Clinical guidelines in NZ state that this is not the correct approach to treatment (MoH HCTAG Advisory Committee).

Theme	Comment
Patients with needle phobia require differing devices to allow treatment.	Clinical advice from the Anti-Infective Subcommittee of PTAC indicated that with training from clinicians such as specialised Hepatitis C nurses, device differences could be overcome. Also, no patients are changing medication as a result of this proposal
Patients with Hepatitis C genotype 3 should be extended to 48 weeks for patients who have a early virological response but do not have a rapid virological response.	PHARMAC staff took clinical advice on the special authority guidelines. Currently Pegasys is only indicated for 24 weeks of treatment for genotypes 2 and 3 only. We would be prepared to review this if the indication changes.
The current duration of treatment for Hepatitis C genotypes 1,4,5 and 6 is 11 months whereas published data indicates 48 weeks treatment duration.	PHARMAC staff acknowledge this response and have amended the Special Authority accordingly.
PHARMAC should introduce mandatory stopping rules for treatment of Hepatitis C.	PHARMAC staff have included additional notes regarding the cessation of treatment rather than adding additional paperwork to this area.

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