

# NSW/QLD EXCEPTIONAL DRUGS LIST COMMITTEE

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## CIRCULAR – EFFECTIVE 1 JANUARY 2009

The NSW/QLD Exceptional Drug List Committee met on 9 December 2008 to undertake its regular review of the list in the light of recent PBS changes.

For information attached is a copy of the EDL – **effective 1 January 2009 – this edition supercedes all previous versions of the EDL.**

**Please ensure that this information is forwarded to ICU/CCU/Radiology/Pharmacy and all other appropriate personnel within your organisation.**

1 May 2008 – 1 July 2008 PBS Changes

There were no additions or deletions announced in the Summary of Changes for 1 May, 1 June or 1 July 2008, which impact on the EDL.

1 August 2008 – PBS Changes

The following change in the 1 August 2008 Summary of PBS changes was noted which requires an amendment to the Authority Restriction Column as detailed below:-

**EDL Code: 5720 – Fludarabine (Fludara) – Oncology – 50 mg (Quantity 5) Parenteral.**

The following comment in the EDL Authority Restriction column has been added:

*B-cell chronic lymphocytic leukaemia in combination with cyclophosphamide where the patient has advanced disease (Binet Stage B or C) or evidence of progressive Stage A disease.*

1 September 2008 – 1 October 2008 PBS Changes

There were no additions or deletions announced in the 1 September or 1 October 2008 Summary of PBS Changes which impact on the EDL.

1 November 2008 – PBS Changes

**Natalizumab**, solution concentrate for I.V. infusion 300mg in 15 mL (Tysabri)

This drug, now S100, is used for multiple sclerosis for patients meeting qualifying conditions. Neurologists prescribing Natalizumab under the PBS listing must be listed with the Tysabri Australian Prescribing Program.

Whilst this does not impact on the EDL, the EDL Committee agreed that it should be noted in this Circular for information.

1 December 2008 – PBS Changes

Two amendments in the December PBS Summary of Changes affect the IPU page of the EDL as under:

**Addition of Special Conditions/Comments Column to IPU Page:**

**Zoledronic Acid (*Aclasta*)**, Solution of IV infusion 5 mg (as monohydrate) in 100mL

*Authority Required:*

- Treatment as the sole PBS-Subsidised anti-resorptive agent for established osteoporosis in men and women with fracture due to minimal trauma.
- In all cases, the fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.
- Only one treatment each year for three consecutive years per patient will be PBS subsidised.

**Zoledronic Acid (*Zometa*)**

*S100:*

Multiple myeloma; Bone metastases from Breast Cancer; Bone metastases from hormone-resistant prostate cancer with demonstration of biochemical progress of disease despite maximal therapy with hormone treatments; Treatment of hypercalcaemia of malignancy refractory to anti-neoplastic therapy.

EDL Amendments as a result of PBS Changes

Amendments to the EDL to reflect PBS changes have been made – the updated list is dated *1 January 2009*. The EDL Committee recommends that the current edition of the EDL be referred to at all times.

EDL Guidelines Review

The EDL Committee considers that irrespective of contractual arrangements between some funds and hospitals, the EDL Committee continues to have relevance in the current environment. At its December meeting, the Committee finalised its review of the current guidelines, and a copy of the endorsed revised guidelines is attached for information.

The EDL Committee has identified that its key activities in the future will be to:

- Maintain the EDL as an industry resource document for the private health sector
- Review the EDL regularly and provide feedback to the industry on relevant PBS amendments affecting the list
- Consider applications from hospitals and health funds in relation to Exceptional Drugs as defined in Appendix A of the revised Guidelines
- Maintain a regime for Individual Patient Usage (IPU) assessment and review of usage
- Conduct relevant surveys to improve understanding regarding drugs in use within the private sector
- Provide technical advice to Government and industry peak bodies and nominate appropriate personnel to relevant external Committees (e.g. Highly Specialised Drugs Working Party – HSDWP)
- Provide an educational role for the sector and a forum to address private sector issues associated with Exceptional Drugs and the PBS including the Highly Specialised Drugs Program.
- To review and disseminate relevant information from the Australian Drug Evaluation Committee (ADEC), the Therapeutic Goods Administration (TGA) and any other relevant agencies
- Engage with suppliers and providers where appropriate to review current practice.

PB 123 Of 2008 – Trastuzumab (Herceptin) – effective 1 December 2008.

*Schedule 1 of PB 123 of 2008 contains specific information regarding authority applications as noted below:*

The total duration of PBS-subsidised treatment (initial plus continuing) that will be authorised is 52 weeks.

Authority applications for initial treatment must be made in writing and must include:

- a. Completed authority prescription form
- b. A completed Early Breast Cancer – PBS Supporting Information Form which includes:
  - (i) A copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH) and
  - (ii) A copy of the signed patient acknowledgement form

The medical practitioner should request sufficient quantity based on the weight of the patient to provide for a maximum of 3 weeks' treatment (equivalent to the loading dose for the 3-weekly regimen, and the loading dose and 2 weekly doses for the one-weekly regimen).

The Commonwealth will only provide a subsidy for a total of 52 weeks, therefore following completion of 17 x 3 weekly cycles, the Commonwealth will only approve ONE week of the last supply.

THE NEXT MEETING WILL BE HELD ON TUESDAY 7 APRIL 2009

HOSPITALS/FUNDS WISHING TO SUBMIT AN APPLICATION FOR LISTING ON THE EDL SHOULD FORWARD TO PHAQ NO LATER THAN FRIDAY 13 MARCH 2009.  
APPLICATION FORMS ARE AVAILABLE BY CONTACTING  
LUCY FISHER ON 0417 824 626 OR (07) 3279 7600

**LUCY FISHER  
SECRETARY – EDL COMMITTEE**

**Attachments:**

- **EDL Update – 1 January 2009**
- **Revised EDL Guidelines – Endorsed December 2008**