

High-cost drugs, off-label use and individual patient approvals.

James Williamson

Kerry McHale

WADEP

(Western Australian Drug Evaluation Panel)

- ▶ Reviews submissions for listing of high-cost drugs on the public hospital formularies.
- ▶ Independent assessment of clinical efficacy and cost-effectiveness.
- ▶ Ensures equal access to high-cost drugs across tertiary centres.

WADEP Activity

Recommended for approval

Adalimumab (arthritis & Crohn's disease)
Bortezomib (multiple myeloma)
Etanercept (arthritis)
Everolimus (lung or heart-lung transplantation)
Infliximab (psoriasis, Crohn's disease, arthritis & ankylosing spondylitis)
Pemetrexed (NSCLC & mesothelioma)
Posaconazole (fungal infections)
Pregabalin (neuropathic pain)
Rituximab (non-Hodgkin's lymphoma x2)
Risperidone LAI (schizophrenia)
Trastuzumab (early breast cancer)
Vinorelbine (advanced breast cancer & NSCLC)

Not Approved

Alefacept (psoriasis)
Anakinra (arthritis)
Carmustine wafers (malignant glioma)
Cinacalcet (secondary hyperparathyroidism)
Gefitinib (NSCLC)
Lapatinib (advanced breast cancer)

25 Submissions (18 drugs) since August 2002.

WADEP approved drugs & PBS listing

Drug Name	WADEP Indication	PBS Listing
Adalimumab	arthritis & Crohn's disease	S85 arthritis (AS, PA, RA)
Bortezomib	multiple myeloma	S85 multiple myeloma
Etanercept	arthritis	S85 arthritis (AS, PA, RA) & psoriasis
Everolimus	lung or heart-lung transplantation	S85 & S100 renal & cardiac transplantation
Infliximab	psoriasis, Crohn's disease, arthritis & ankylosing spondylitis	RPBS arthritis (RA). S100 arthritis (AS, PA, RA), Crohn's disease & psoriasis.
Pemetrexed	NSCLC & mesothelioma	S85 NSCL (since 2004) & mesothelioma
Posaconazole	fungal infections	No listing
Pregabalin	neuropathic pain	RPBS neuropathic pain
Rituximab	B-Cell non-Hodgkin's lymphoma	S85 B-cell NHL S100 arthritis (RA)
Risperidone LAI	schizophrenia	S85 schizophrenia
Trastuzumab	early breast cancer	S100 early breast cancer
Vinorelbine	advanced breast cancer & NSCLC	S85 advanced breast cancer & NSCLC

Drugs rejected by WADEP/WATAG & their current (R)PBS listing

Drug Name	WADEP Indication	PBS Listing
Alefacept	psoriasis	RPBS psoriasis
Anakinra	arthritis	S85 arthritis (RA)
Carmustine wafers	malignant glioma	S85 Glioblastoma multiforme
Gefitinib	NSCLC	S85 NSCLC
Cinacalcet	secondary hyperparathyroidism	PBS recommendation made for listing – pending listing.
Lapatinib	advanced breast cancer	PBS recommendation made for listing- pending listing.

Recent Submissions (2007/08)

- ▶ Bortezomib – recommended for listing 7/6/07 following PBS listing (previously rejected)
- ▶ Cetuximab – recommended for listing 2/8/07
- ▶ Adalimumab – recommended for listing 20/9/07
- ▶ Lapatinib – submission rejected 22/11/07
- ▶ Omalizumab – currently under consideration

Pemetrexed

- ▶ Submission received 24/5/2005 for treatment of patients with malignant pleural mesothelioma.
- ▶ WADEP positive recommendation approval completed 27/10/2005.
- ▶ PBAC rejected on the basis of unfavourable cost-effectiveness (March & November 2005).
- ▶ PBAC recommended for S85 listing November 2007 (Available S85 for NSCLC since 2004).

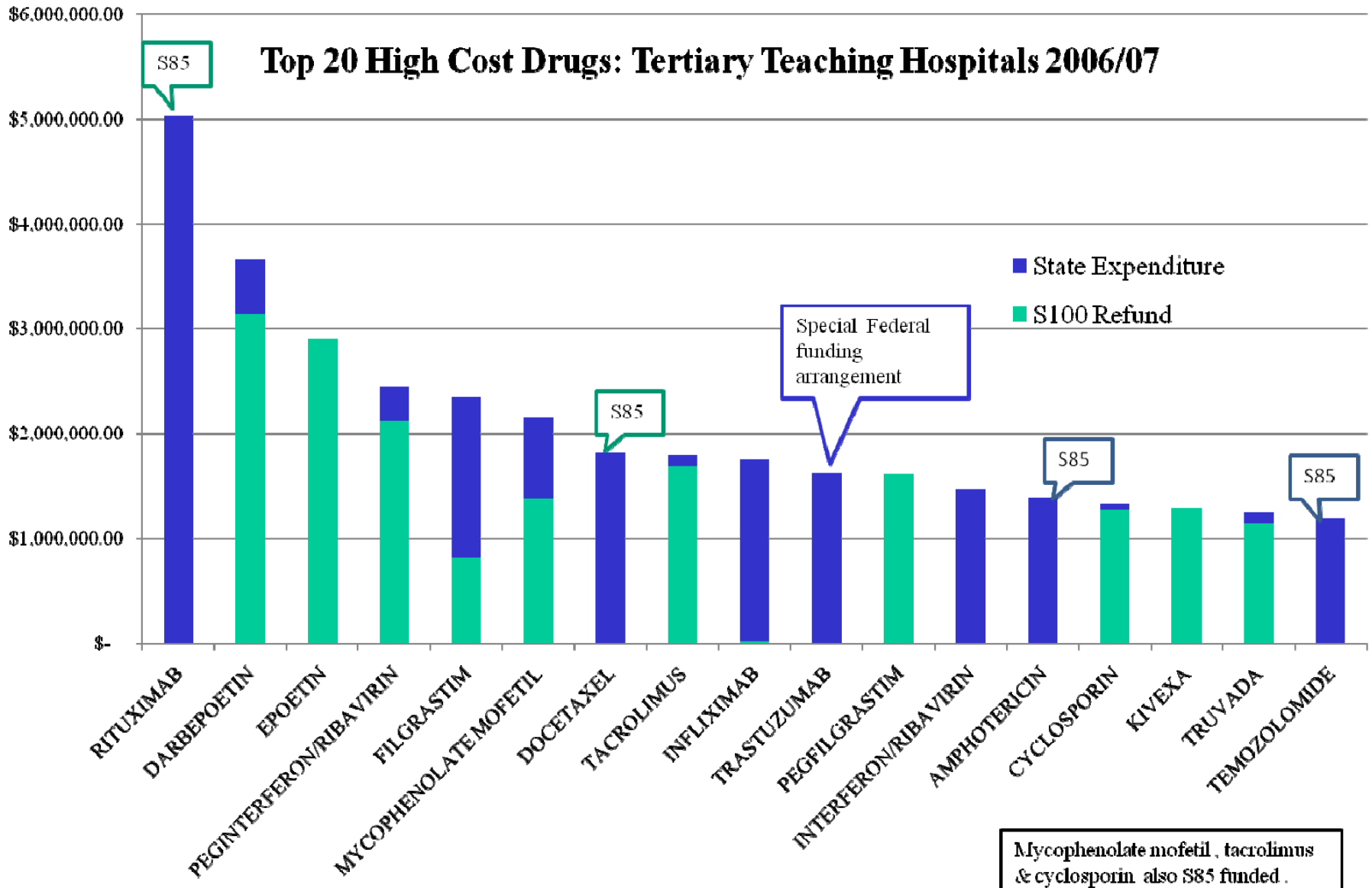
Pemetrexed

- ▶ Projected annual cost to State to treat mesothelioma prior to PBS listing \approx \$300,000.
- ▶ Total expenditure on pemetrexed (NSCLC & mesothelioma) at tertiary teaching hospitals:
 - 2004/05 \approx \$150,000
 - 2005/06 \approx \$200,000
 - 2006/07 \approx \$800,000.

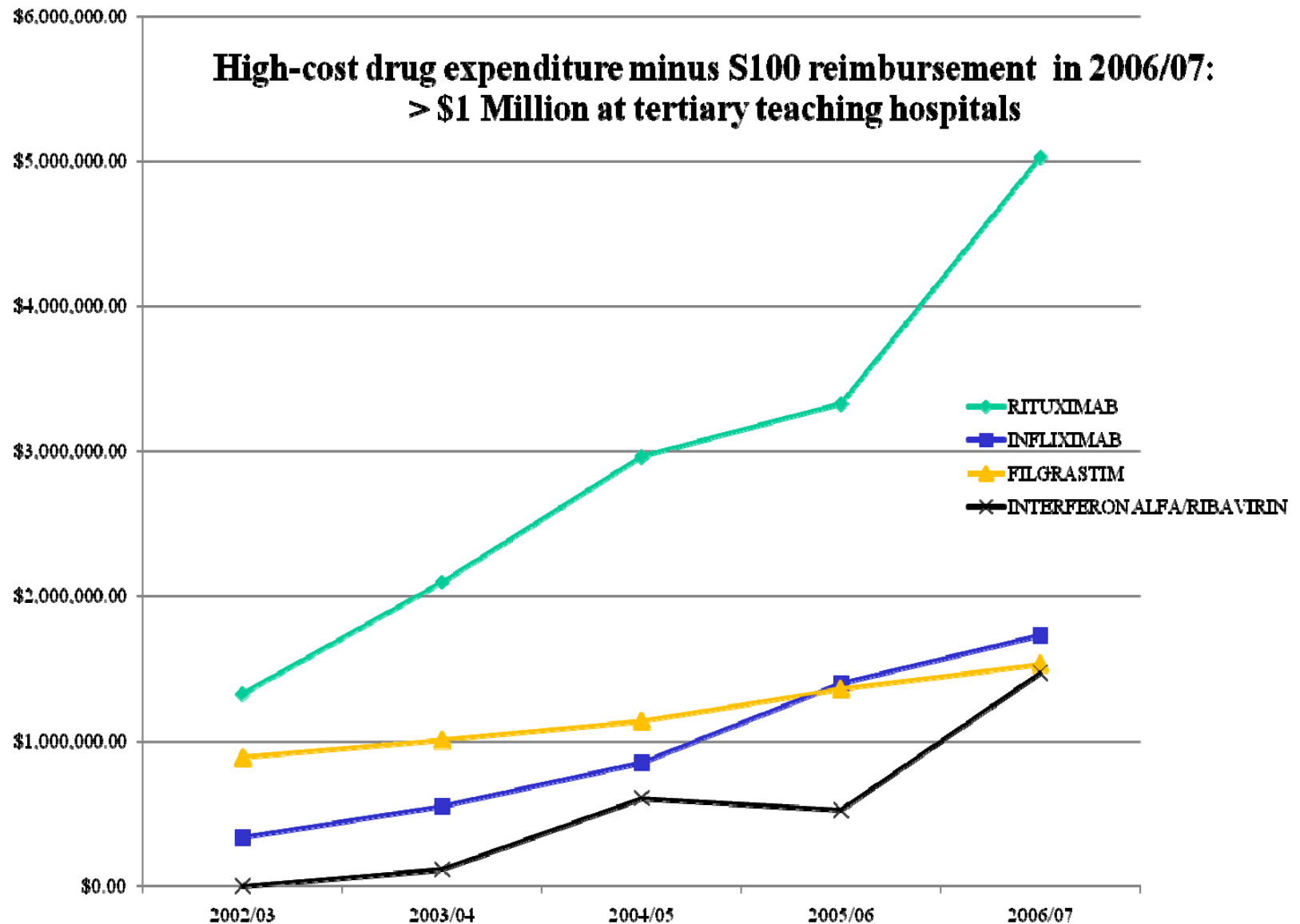
Pemetrexed

- ▶ Pemetrexed use variable across institutions:
 - RPH \approx 2006/07 \approx \$213,000
 - SCGH 2006/07 \approx \$570,000
 - SCGH Data from 01/11/06 - 31/07/07.
 - Total number of dispensings: 80 (160 vials)
 - Number of PBS dispensings: 22 (44 vials)
 - Total \$PBS reimbursements: \$64,000 for 2006/07
 - Estimate approx 3/4 pemetrexed use in mesothelioma at SCGH.

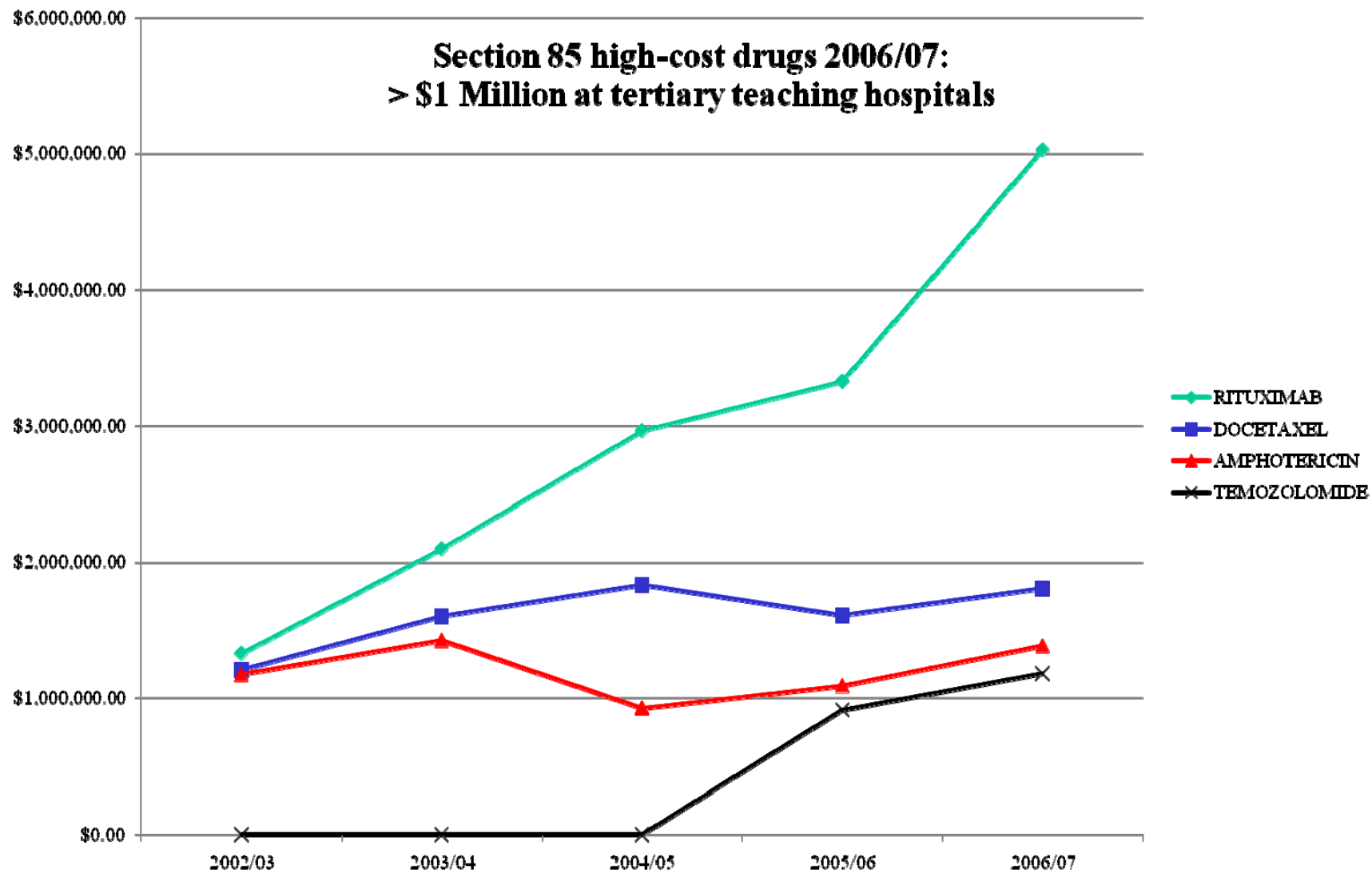
Top 20 High Cost Drugs: Tertiary Teaching Hospitals 2006/07



High-cost drug expenditure minus \$100 reimbursement in 2006/07: > \$1 Million at tertiary teaching hospitals



**Section 85 high-cost drugs 2006/07:
> \$1 Million at tertiary teaching hospitals**



Rituximab

▶ PBS Section 85

- Relapsed or refractory low-grade B-cell NHL.
- Relapsed or refractory follicular B-cell NHL.
- Untreated, CD20 positive, diffuse large B-cell NHL.
- Symptomatic patients with previously untreated, CD20 positive, Stage III or IV, follicular, B-cell NHL.

▶ PBS Section 100

- Rheumatoid arthritis

Rituximab

- ▶ Many non-PBS/non-WADEP/non-formulary listed uses in Haematology and Immunology.
 - Subject to Individual Patient Approval (IPA)
 - Total of 46 IPAs in 2007 at tertiary teaching hospitals
- ▶ No S100 reimbursement to public hospitals for any indication.
- ▶ Section 85 reimbursement for PBS prescribing hospitals only - SCGH.

Relapsed Idiopathic Thrombocytopenic Purpura
Mantle Cell Lymphoma
Chronic Lymphocytic Leukemia
Burkitt's Lymphoma CD 20+ (non-Hodgkins Lymphoma)
Idiopathic Uveitis
Immune Thrombocytopenia
Severe Refractory Lupus Erythematosus
Stiff Person Syndrome
Stiff Person Syndrome
Burkitt's Lymphoma
Autoimmune myositis & myocarditis (Anti-synthetase Syndrome)
Chronic Lymphocytic Leukaemia
Refractory Lupus Nephritis not controlled with cyclophosphamide
Retro-orbital lymphoid hyperplasia
Hepatitis C with associated cryoglobulinemia & vasculitis

Relapsed Idiopathic Thrombocytopenic Purpura
Essential Cryoglobulinemia
Chronic Lymphocytic Leukemia
Resistant Dermatomyositis
Multiple Sclerosis Acute Aggressive optical, spinal & cerebral demyelination
Mantle Cell Lymphoma
Wegener's Granulomatosis
Relapsed Diffuse Large B-Cell Non-Hodgkin's Lymphoma
Refractory Immune Thrombocytopenia
Refractory Immune Thrombocytopenia
Acquired Haemophilia (Factor 8 Inhibitor titers) with bleeding
Behcet's Disease
Severe Refractory Lupus Erythematosus
Sjogren's syndrome (also has myeloma)
Neuromyelitis of Optic Nerve
Cryoglobulinemia

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Rituximab

- ▶ Expenditure at tertiary teaching hospitals 2006/07:
 - FH \$1.5 million
 - RPH \$1.5 million
 - SCGH \$1.8 million
- ▶ PBS recovery of costs since PBS prescribing at SCGH:
 - 2006/07 approx \$840,000

Individual Patient Approval (IPA)

- ▶ Individualised approval systems across hospitals.
- ▶ Different policies for repeated applications.
 - One application and then formal WADEP submission (RPH)
 - Controlled and monitored access via IPA before formal WADEP submission requested (SCGH).
- ▶ Each hospital trying to control access to non-formulary drugs.

IPA: Issues identified

- ▶ Different practices and policies at each centre.
- ▶ Limited data collection and clinical feedback.
- ▶ Uncertainty about outcomes and effectiveness.
- ▶ Lower than anticipated numbers of applications proceeding to WADEP for review.

IPA: Proposal

- ▶ Implementation of an online approval system.
 - WADEP approved and non-formulary listed drugs.
 - Online drug ordering system using iCM.
 - Simple and largely automated.
 - Standardised across centres.
- ▶ Improved monitoring, clinical feedback and data collection.

Questions?

