High Cost Medicines

Overview of governance and evaluation in South Australia

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Government of South Australia
SA Health

Overview

- Statewide medicines governance
- SA Medicines Evaluation Panel
  - High Cost Medicines
- Processes
- Outcomes
- Recent updates
- Opportunities
- Challenges

Chief Pharmacist Office

- state-wide leaders for medicines legislation, policy and governance programs for pharmacy, medicines and health technology assessment
- to ensure best possible outcomes for all South Australians through **ensuring equitable access to safe, effective and cost-effective care.**
- includes medicines access, safety and quality, commonwealth committees/ agreements, state government commitments
- enhancing medicines use and pharmacy role in primary care / hospital avoidance, scope of practice development

State level - Medicines and Technology Issues

- quality and safety of care
- Innovation, demand
- health technology is the main driver of hospital costs
  - 40-50% of cost increases are attributed to new technologies or the intensified use of old ones
  - More costly than ever, potentially life saving, no alternatives, early entry, marginal benefit
  - Affordability, access and funding schemes
- Equity of access
  - Patient, clinician
- Consistency and efficiency
  - policies, decision-making and resource allocation
  - Value-based care

Funding of Pharmaceuticals

> Commonwealth Government

- PBS
  - Prescription medicines approved as cost effective for use by all Australians
  - Community-based care ie not hospital only
  - S100 Highly Specialised Drugs Scheme, EFC
  - Uncapped expenditure
    - > Up to 15% pa growth, various strategies to reduce

> State Governments

- Hospital funding
  - State or local hospital drug committees and formularies
  - “Capped” budgets
  - 2004/5 – AHCA PBS Reforms, 2009/10 – SA Health
  - Non-PBS and inpatient treatments
    - > Complex care, increasing costs

Medicines may not be listed on the PBS

- Off label , non TGA approved
- Insufficient evidence of efficacy or safety
- efficacy or safety are inferior to current available options, comparators
- Not cost-effective
- Not submitted by company
- Rare conditions
  - low numbers, unable to adequately power clinical trials
- **Hospital only conditions**
  - Inpatient treatments, leading /early adoption
  - Decision-making at local level

South Australian Medicines Advisory Committee (SAMAC)

- Peak medicines expert governance and advisory committee to SA Health
  - reporting to the Health Clinical Executive Committee
  - Established July 2010
- Promotes the appropriate, equitable, safe and cost-effective use of medicines
- Provides overarching governance of medicines policy and agenda
- Linkage to national committees/programs

SAMAC

- Chaired by Professor Randall Faull
  - E/Prof Anne Tonkin
  - Inaugural chair E/Prof Lloyd Sansom AO
- Convenor – Chief Pharmacist

Membership

- Chairs, LHN Drug and Therapeutic Committees
  - 4 Metropolitan and Regional (centralised)
- LHN Directors of Pharmacy
- SA Health Chief Medical Officer, Chief Psychiatrist, Chief Nurse, Director,OCP
- Representatives of primary care and private health care sectors including GPs, community pharmacy
- Consumer representatives
- Senior Pharmacist/Exec officer

SAMAC Sub-committees

- multidisciplinary expert standing committees and working groups
- address specific medicines policy, advice, guidelines and functions
- ensure opportunities for discussion, debate, and evaluation of medicines issues.

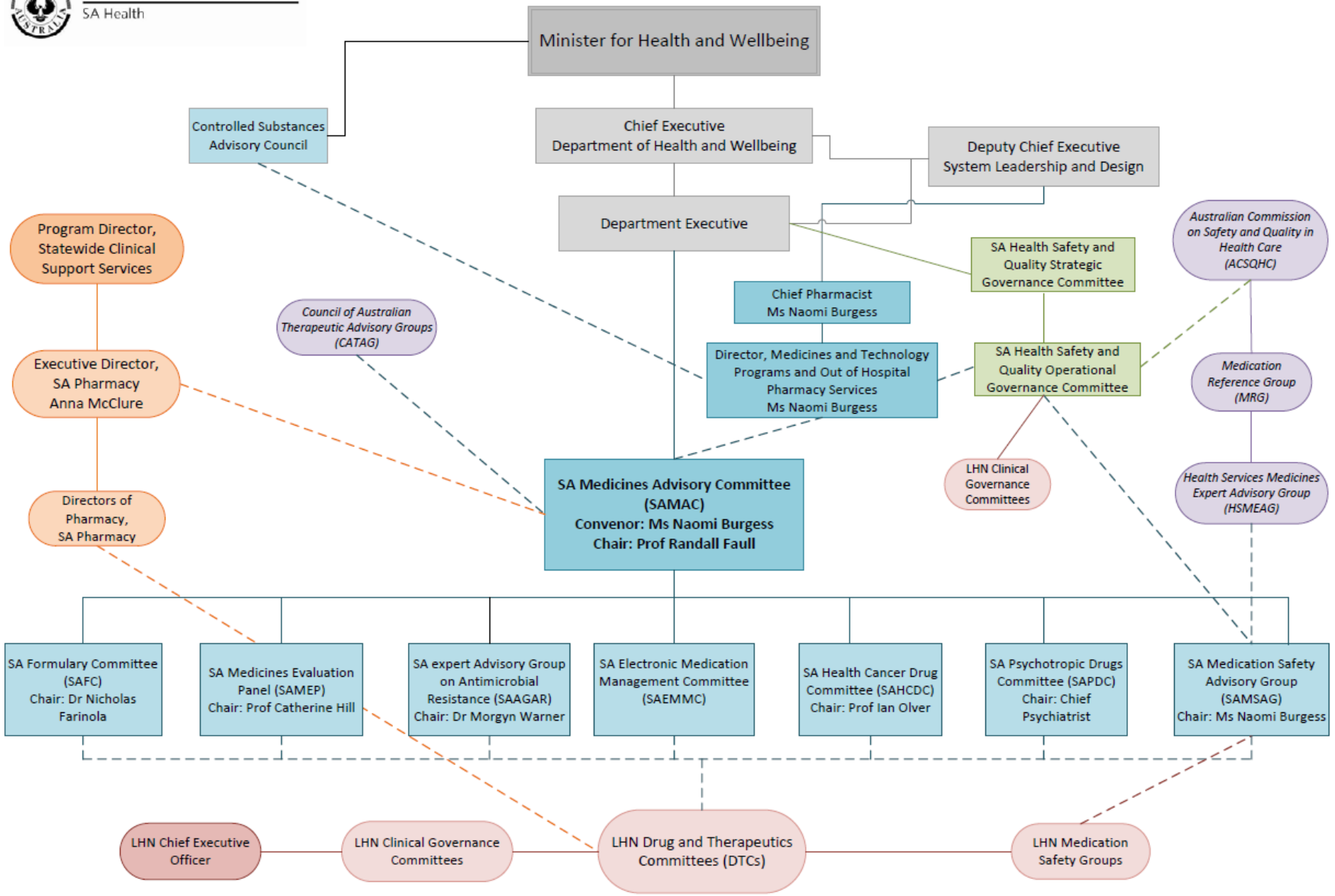
Current sub-committees:

- SA Expert Advisory Group on Antimicrobial Resistance (SAAGAR)
- **SA Medicines Evaluation Panel (SAMEP)**
- SA Formulary Committee (SAFC)
- SA Medication Safety Advisory Group (SAMSAG)
- SA Chemotherapy Drug Committee
- SA Psychotropic Drugs Committee
- SA Electronic Medicines Management Committee

For more information: www.sahealth.sa.gov.au/samac

Government of South Australia
SA Health

SA Health Medicines Governance Structure



Background - Equity of access to medicines

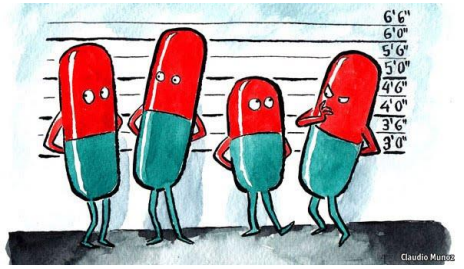
- SA Health determined to ensure that patient access to safe, clinically-appropriate and cost-effective medicines is not dependent on which hospital the patient attends.
- In 2011, implemented policy framework to ensure all public hospitals provide a consistent, evidenced-based approach to the management of medicines
- In particular High Cost Medicines, should be available, based on local clinical advice and budget.
- Previously, each hospital Drug and Therapeutics Committee made its own decisions on which medicines were available and under what conditions

Statewide Formulary for High Cost Medicines Policy Directive

Statewide Evaluation of High Cost Medicines

Since 2011

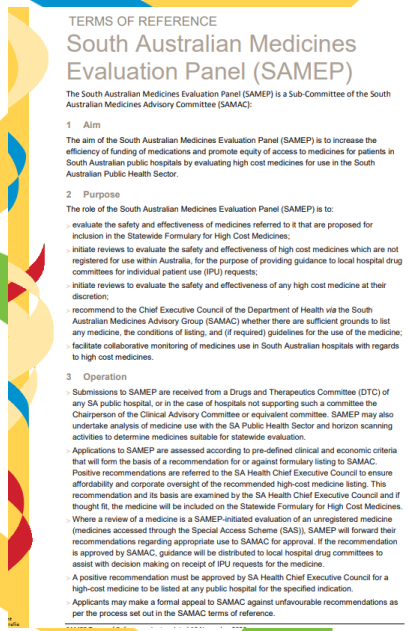
- evaluation of High Cost Medicines by statewide panel - SA Medicine Evaluation Panel (SAMEP)
- linked to a Statewide Formulary for High Cost Medicines
- LHN DTC approval of High Cost Medicines for Individual Patient Use (IPU)



Principle aims

The SAMEP /HCM Formulary aims to address the four key concerns about use of High Cost Medicines in South Australian Public Hospitals:

- Promote equity of access to South Australians in the public health system
- Evaluating medicines to ensuring that safe, effective and cost-effective medicines are used within SA Health
- Reducing decision-making pressure and duplication of effort in assessing High Cost Medicines
- Ensuring that High Cost Medicines are used in accordance with specific evidenced-based guidelines



TERMS OF REFERENCE

South Australian Medicines Evaluation Panel (SAMEP)

The South Australian Medicines Evaluation Panel (SAMEP) is a Sub-Committee of the South Australian Medicines Advisory Committee (SAMAC):

1 Aim

The aim of the South Australian Medicines Evaluation Panel (SAMEP) is to increase the efficiency of funding of medications and promote equity of access to medicines for patients in South Australian public hospitals by evaluating high cost medicines for use in the South Australian Public Health Sector.

2 Purpose

The role of the South Australian Medicines Evaluation Panel (SAMEP) is to:

- evaluate the safety and effectiveness of medicines referred to it that are proposed for inclusion in the Statewide Formulary for High Cost Medicines;
- initiate reviews to evaluate the safety and effectiveness of high cost medicines which are not registered for use within Australia, for the purpose of providing guidance to local hospital drug committees for individual patient use (IPU) requests;
- initiate reviews to evaluate the safety and effectiveness of any high cost medicine at their discretion;
- recommend to the Chief Executive Council of the Department of Health via the South Australian Medicines Advisory Group (SAMAC) whether there are sufficient grounds to list any medicine, the conditions of listing, and (if required) guidelines for the use of the medicine;
- facilitate collaborative monitoring of medicines use in South Australian hospitals with regards to high cost medicines.

3 Operation

- Submissions to SAMEP are received from a Drugs and Therapeutics Committee (DTC) of any SA public hospital, or in the case of hospitals not supporting such a committee the Chairperson of the Clinical Advisory Committee or equivalent committee. SAMEP may also undertake analysis of medicine use with the SA Public Health Sector and horizon scanning activities to determine medicines suitable for statewide evaluation.
- Applications to SAMEP are assessed according to pre-defined clinical and economic criteria that will form the basis of a recommendation for or against formulary listing to SAMAC. Positive recommendations are referred to the SA Health Chief Executive Council to ensure affordability and corporate oversight of the recommended high-cost medicine listing. This recommendation and its basis are examined by the SA Health Chief Executive Council and if thought fit, the medicine will be included on the Statewide Formulary for High Cost Medicines.
- Where a review of a medicine is a SAMEP-initiated evaluation of an unregistered medicine (medicines accessed through the Special Access Scheme (SAS)), SAMEP will forward their recommendations regarding appropriate use to SAMAC for approval. If the recommendation is approved by SAMAC, guidance will be distributed to local hospital drug committees to assist with decision making on receipt of IPU requests for the medicine.
- A positive recommendation must be approved by SA Health Chief Executive Council for a high-cost medicine to be listed at any public hospital for the specified indication.
- Applicants may make a formal appeal to SAMAC against unfavourable recommendations as per the process set out in the SAMAC terms of reference.

SAMEP

Membership

- Chair – Dr Tilenka Thynne
  - Inaugural Chair – Prof Catherine Hill
- Program Manager – Dr Agnes Vitry (0.5FTE)
- 8 senior clinicians with an interest in medicines use (ICU, oncology, paediatrics, neurology, immunology, haematology, pharmacology)
- 3 clinical pharmacists
- health economist, medical ethicist, consumer representatives, HTA experts

- Meet every 2months to review high cost medicine formulary applications
- Facilitate statewide monitoring of IPUs

In scope

High cost medicine

≥$10,000 per patient per treatment course or per year;

or

≥$100,000 for an individual hospital per year;

or

≥$300,000 within the SA public health system per year.

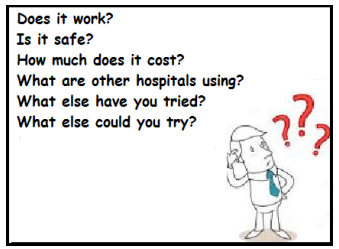
Exemptions: clinical trials, compassionate use, PBS-funded medicines, low cost/high volume drugs

- 3 x IPUs or formulary submission
- High cost drugs often
  - New & emerging drugs, indications
  - off-label
  - Small patient populations (incl refractory disease)
  - Treatment in the tertiary setting

HCM evaluation

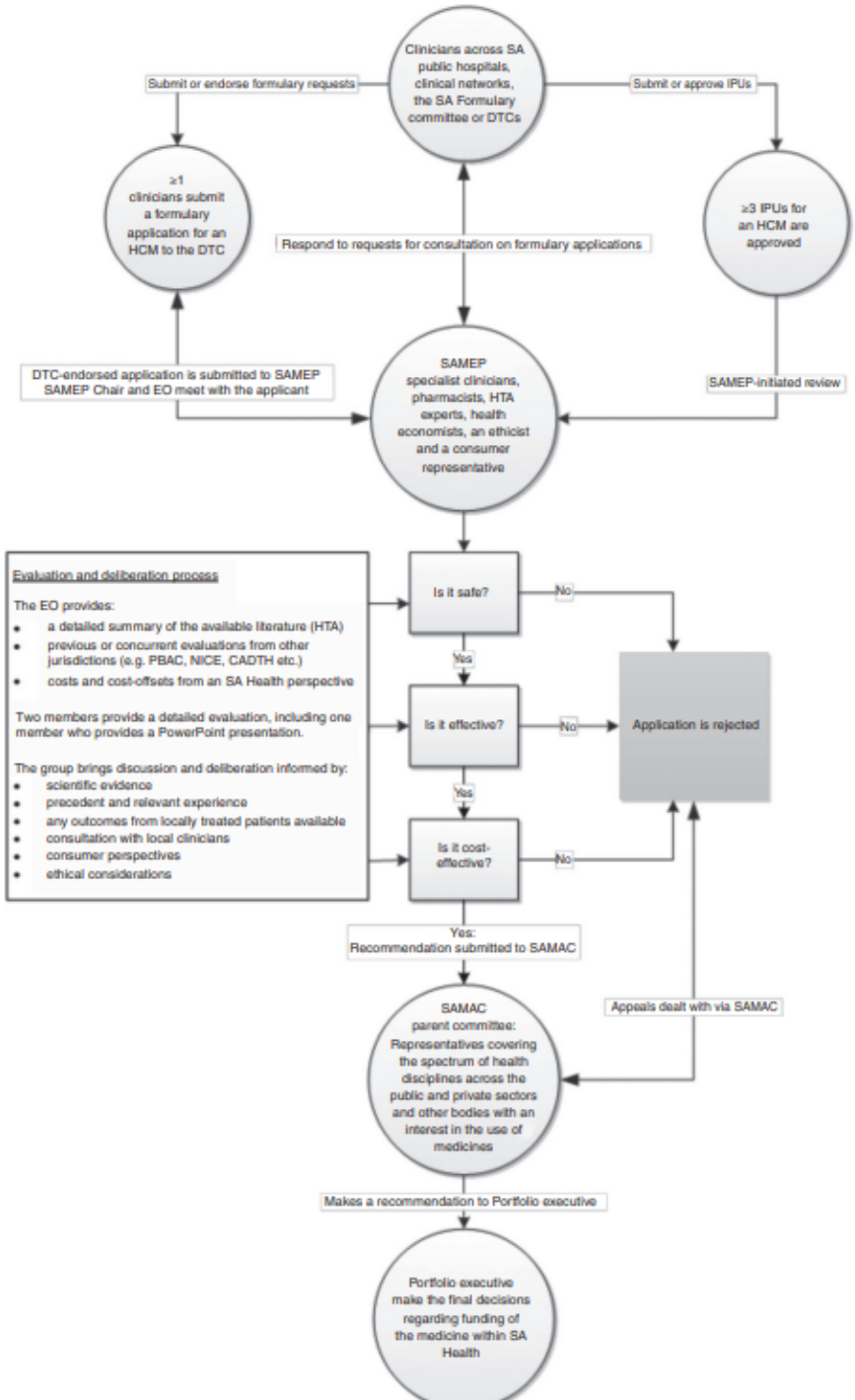
> Consistent, transparent framework

- Clinician application via DTC (or SAMEP initiated)
- Detailed request incl treatment pathway
- Executive Summary
  - Evidence review using recognised scientific HTA approaches
  - Expert clinical opinion, key stakeholders
  - other states, jurisdictions (eg CADTH, NICE, EMA, SMC)
  - Cost analysis, offsets, cost-effectiveness analysis (where data available)
  - local outcome data (where available eg IPUs)
- Presentation of evidence by 2 panel members
- Development of recommendations



Recommendation to the Department of Health

- SAMAC considers and provides advice to Health Clinical Executive :
  - Recommendation for, or against formulary listing.
  - Protocol/Clinical guidelines for use, prescribing restrictions
  - Required monitoring incl outcomes
  - Details of evaluation process and reasons for recommendation made
  - Predicted patient numbers and budget impact
- Executive assess the affordability, LHN input
- If approved, advice provided to the clinician (s)
  - decision summaries easily accessible to stakeholders (website)
- decisions are revisable in light of new evidence (process for appeal/revision in place)

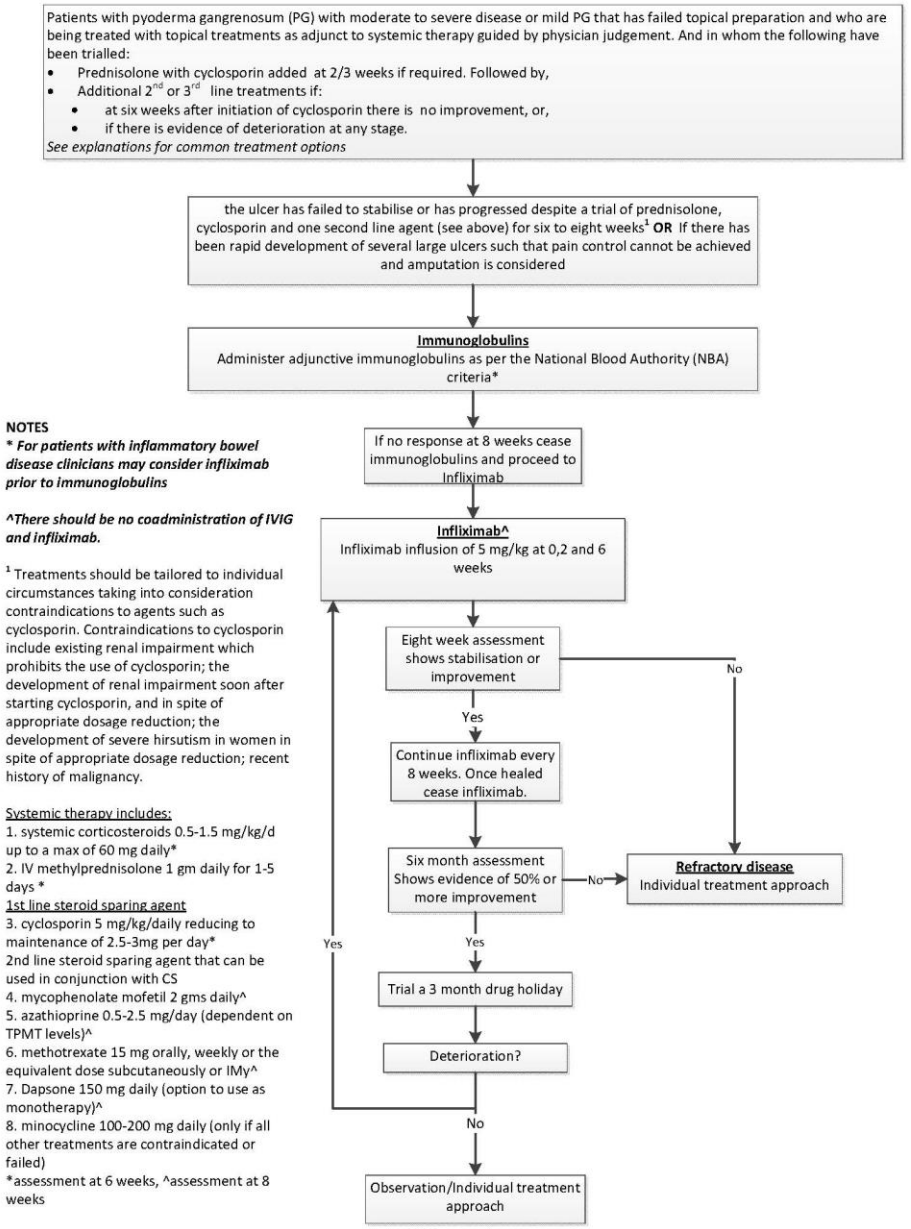

Clinicians across SA public hospitals, clinical networks, the SA Formulary committee or DTCs
Submit or endorse formulary requests
Submit or approve IPUs
≥1 clinicians submit a formulary application for an HCM to the DTC
≥3 IPUs for an HCM are approved
Respond to requests for consultation on formulary applications
DTC-endorsed application is submitted to SAMEP
SAMEP Chair and EO meet with the applicant
SAMEP-initiated review
SAMEP specialist clinicians, pharmacists, HTA experts, health economists, an ethicist and a consumer representative
Evaluation and deliberation process
The EO provides:
a detailed summary of the available literature (HTA)
previous or concurrent evaluations from other jurisdictions (e.g. PBAC, NICE, CADTH etc.)
costs and cost-offsets from an SA Health perspective
Two members provide a detailed evaluation, including one member who provides a PowerPoint presentation.
The group brings discussion and deliberation informed by:
scientific evidence
precedent and relevant experience
any outcomes from locally treated patients available
consultation with local clinicians
consumer perspectives
ethical considerations
Is it safe?
No
Yes
Is it effective?
No
Application is rejected
Yes
Is it cost-effective?
No
Yes:
Recommendation submitted to SAMAC
Appeals dealt with via SAMAC
SAMAC parent committee: Representatives covering the spectrum of health disciplines across the public and private sectors and other bodies with an interest in the use of medicines
Makes a recommendation to Portfolio executive
Portfolio executive make the final decisions regarding funding of the medicine within SA Health

ealth

Contents

ealth

Treatment pathway - Infliximab for Pyoderma Gangrenosum



Eligibility Criteria

Statewide High Cost Medicines Formulary

Rituximab

Rituximab for adults with biopsy proven idiopathic membranous nephropathies who are refractory to standard treatment. The dose is two doses of 1000 mg IV rituximab given 14 days apart

The following information is required to be provided by the **prescriber** prior to dispensing of the high cost medicine:

Hospital:

Patient UR number:

Prescriber eligibility for rituximab: (both criteria must be ticked)

1. ☐ **Consultant Nephrologist**

   and

2. ☐ **Prescriber agrees to forward the following outcome measures to the SAMEP executive officer at 3, 6, and 12 months and annually thereafter:**
   - 24 hour proteinuria
   - Estimated Glomerular Filtration Rate (eGFR)

Patient eligibility for rituximab in patients who are rituximab naive: (all six criteria must be ticked)

1. ☐ **Patient has been provided with written information about the intended treatment with the rituximab.**

   and

2. ☐ **Urinary protein excretion is persistently > 4g/day**
   Specify most recent 24 hour proteinuria:

   and

3. ☐ **Patient is symptomatic**

   and

4. ☐ **Patient is receiving best supportive care including dietary modification, angiotensin-converting-enzyme inhibitors or angiotensin II receptor blockers, and diuretics.**

   and

5. ☐ **Patient has failed six months of prednisolone and cyclophosphamide given concurrently**
   Specify six month 24 hour proteinuria:

   OR patient has an absolute contraindication to treatment (tick those applicable)
   - ☐ Women of reproductive age who wish to maintain reproductive fertility
   - ☐ Has severe myelosuppression in spite of appropriate dosage reduction
   - ☐ Severe nausea in spite of appropriate dosage reduction and anti-emetic agents
   - ☐ Past history of urinary bladder cancer
   - ☐ Significant cumulative exposure to cyclophosphamide of more than or equal to 25gms
   - ☐ If other please specify:

   and

6. ☐ **Patient has failed six months of a calcineurin inhibitor (cyclosporin or tacrolimus)**
   Specify six month 24 hour proteinuria:

   OR patient has an absolute contraindication to treatment (tick those applicable)
   - ☐ Existing renal impairment which prohibits the use of cyclosporin
   - ☐ The development of renal impairment soon after starting cyclosporine, and in spite of appropriate dosage reduction
   - ☐ The development of severe hirsutism in women in spite of appropriate dosage reduction
   - ☐ If other please specify:

Patient eligibility for rituximab in patients who have previously received rituximab: (all six criteria must be ticked)

1. ☐ **Patient has been provided with written information about the intended treatment with the rituximab.**

   and

2. ☐ **Urinary protein excretion is persistently > 4g/day**
   Specify most recent 24 hour proteinuria:

   and

3. ☐ **Patient is symptomatic**

   and

4. ☐ **Patient is receiving best supportive care including dietary modification, angiotensin-converting-enzyme inhibitors or angiotensin II receptor blockers, and diuretics.**

   and

5. ☐ **Patient has relapsed after previously demonstrating a complete or partial response to rituximab having persisted for a minimum of 12 months**

   and

6. ☐ **Prescriber has provided, for this patient, the following outcomes pertaining to the initial treatment with rituximab:**
   - ☐ 24 hour proteinuria at 3,6, and 12 months (and annually thereafter)
   - ☐ eGFR at 3,6, and 12 months (and annually thereafter)

The following definitions must be used when completing this form:
Complete Remission - Proteinuria < 0.5 g/d
Partial Remission - Improvement in proteinuria by ≥ 50% and ≤ 3 g/d
Failure – residual proteinuria > 3 g/d and/or improvement in proteinuria < 50%
Relapse – proteinuria in the nephrotic range (>4g/day) and no longer meeting the criteria of complete or partial response in a patient who had previously demonstrated complete or partial response

(a) Eligibility checklist

Vedolizumab

300 mg powder for IV infusion

108 mg/0.68 mL pre-filled syringe for SC injection

Vedolizumab is listed on the SA Medicines Formulary for paediatric patients (aged 6-17 years inclusive, weight > 30 kg) with **moderate to severe refractory Crohn's disease**, or **moderate to severe ulcerative colitis**

- with chronically active or steroid-dependent disease
- who are experiencing a loss of response to anti-TNF medicines despite dose optimisation after measurement of drug levels and antibody levels, and use of immunomodulator medicines

The recommended dosage is 5–6 mg/kg up to 300 mg per dose administered by IV infusion at 0, 2 and 6 weeks and then every 8 weeks thereafter.

The recommended dosage for SC vedolizumab as a maintenance treatment, following at least 2 intravenous infusions, is 108 mg administered by subcutaneous injection once every 2 weeks. The first SC dose should be administered in place of the next scheduled IV dose and every 2 weeks thereafter.

Patients should be reviewed within 6 to 8 weeks of completing the induction regimen, corresponding to 12-14 weeks after initiation of induction treatment. Treatment should be discontinued for patients who have not shown a clinical response by Week 14.

Clinical response has been defined as:
a) Crohn's disease: a decrease in Paediatric Crohn's Disease Activity Index (PCDAI) by at least 15 points from baseline and a PCDAI score ≤ 40
b) Ulcerative colitis: Paediatric Ulcerative Colitis activity index (PUCAI) < 10 points

The following information is required to be provided by the **prescriber** prior to dispensing of the high cost medicine:

Hospital: **Patient name:**

Patient UR number: **Patient date of birth:**

Patient weight:

Prescriber eligibility for vedolizumab:

1. ☐ Specialist paediatric gastroenterologist or consultant physician [internal medicine specialising in gastroenterology) from SA HEALTH IBD services

Patient eligibility for vedolizumab: (All six criteria must be ticked)

1. ☐ Patient has been diagnosed with Crohn's disease or ulcerative colitis Patient initial PCDAI or PUCAI: .....
2. ☐ Patient must have failed to achieve an adequate response or have intolerance to systemic therapies such as azathioprine and 6-mercaptopurine.
3. ☐ Patient must have failed to achieve an adequate response to a tapered course of or have intolerance to oral steroids.
4. ☐ Patient is experiencing primary or secondary loss of response to infliximab despite appropriate therapeutic levels or in the presence of high anti-infliximab antibodies.
5. ☐ Patient 's treatment plan has been discussed at Gastroenterology MDT Date / /
6. ☐ Documentation of the explanations given to the patient and informed consent for off-label use of vedolizumab have been recorded in the case notes.

Outcome assessment (date ../../..)

1. ☐ **Prescriber agrees to provide the following measures of clinical outcomes following an initial 6- month treatment period to the SAMEP executive officer and every following year thereafter:**

• Has the patient had a response? (YES/NO) Please describe the response:
Crohn's disease: current PCDAI:... decrease in PDCAI since treatment start:....
Ulcerative colitis: current PUCAI:....decrease in PUCAI since treatment start:....
C-reactive protein:
Clinical assessment:
Treatments currently received (steroids, immunomodulators):

Is the patient still receiving vedolizumab? If not indicate which treatment are they receiving?

I certify that the above information is correct:

(Prescribers signature)

Date:
Name:
Position:
Department:
Contact/pager number:

Information for pharmacy

This form should be retained in the pharmacy department and a copy forwarded to:

The Executive Officer
South Australian Medicines Evaluation Panel
Medicines and Technology Policy and Programs
Level 1, 101 Grenfell St
Adelaide 5000
(08) 7117 9805
SAMEP@sa.gov.au

For more information:
http://www.sahealth.sa.gov.au/samep

Government of South Australia SA Health

High cost medicine reviews

The Statewide Formulary for High Cost Medicines aims to ensure that eligible patients will have equal opportunity to receive a high cost medicine based upon their clinical condition rather than where they live or what hospital they attend.

All public hospitals must comply with the SA Health Statewide Formulary for High Cost Medicines policy (PDF 281KB) to enhance equity of access within the South Australian public health system.

Application process

Formulary applications for high cost medicines should be forwarded to your hospital Drug & Therapeutics Committee. The application should be signed by the Chair of the committee and then forwarded to South Australian Medicines Evaluation Panel (SAMEP) for review. Further information on submitting a formulary application, see the Information for clinicians on submitting a formulary application for a High Cost Medicine (PDF 1377KB) is provided on the following form. SAMEP will then undergo a systematic process of evaluating the medicine for safety, clinical efficacy and cost-effectiveness. SAMEP will consult with specialist clinicians and seek additional external expertise if required.

Medicines under review

- Formulary application form (DOC 603KB)

If you are require a high cost medicine for a single use, please refer to the Individual patient use (IPU) of high cost medicines page.

For further information on Statewide Formulary for High Cost Medicines, contact the South Australian Medicines Evaluation Panel.

South Australian Medicines Evaluation Panel

Information for clinicians on submitting a formulary application for a High Cost Medicine

Under SA Health policy, formulary applications for High Cost Medicines (HCMs) must be forwarded via the hospital Drug & Therapeutics Committee (DTC) to the South Australian Medicines Evaluation Panel (SAMEP) for evaluation of efficacy & safety, and the cost-effectiveness of the proposed medicine compared to currently available treatment options. This information sheet provides general information to assist SAMEP to complete the evaluation of the formulary application in a timely manner.

Completion of the formulary request form

All requests for a medicine to be included on the statewide High Cost Medicines formulary must be submitted by completing an ***SA Health Medicines Formulary Request Form***.

The completed and signed form must be forwarded to the executive officer of the hospital DTC. If the medicine is considered to be high cost, the DTC will forward the form to the executive officer to SAMEP.

Additional information required

If the HCM has already been used for the proposed indication via requests for Individual Patient Use (IPU), it is expected that details of the historical use within SA Health are provided, including the clinical outcomes of patients who have already been prescribed the medicine. Non-provision of outcome data will likely delay the evaluation process. In addition, SAMEP may request other information to assist their evaluation. Information on local usage is particularly important when the indication is rare, and published data is scarce.

Meeting with the Chair & Executive Officer to SAMEP

On receipt of a HCM formulary application, the Executive Officer to SAMEP will conduct a comprehensive literature search and will complete a summary of the application, highlighting areas of uncertainty. This summary will be forwarded to the applicant together with a meeting request to discuss issues raised and clarify areas of uncertainty prior to the SAMEP meeting.

Consultation

The proposed formulary listing along with a draft clinical pathway or eligibility criteria will be circulated to applicable specialist clinicians with a request for expert opinion and feedback. For specialties represented by a Statewide Clinical Network, consultation will be directly via the Network. In all other cases, the heads of departments at SA public hospitals and the DTCs will be consulted. Lack of consensus among clinicians may also delay the evaluation.

Timeline of review

SAMEP meet every two months to review formulary applications for HCMs. If a decision is possible, the recommendation of the panel will be forwarded to the South Australian Medicines Advisory Committee (SAMAC). In general, the review process will take a minimum of two months.

The progress of the review is dependent upon timely responses to consultation and the provision of any outcome data available for the indication. At any stage in the review process, the applicant may contact the Executive Officer to SAMEP for an update on the progress of the review.

SAMEP is an advisory committee to SAMAC. The role of SAMEP is to evaluate the HCM for efficacy, safety and cost-effectiveness and provide that information to SAMAC and Portfolio Executive, who make the final decisions regarding funding of the medicine within SA Health.

For more information

The Executive Officer
South Australian Medicines Evaluation Panel
Medicines and Technology Policy and Programs
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11 Hindmarsh Sq
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SAMEP@health.sa.gov.au

http://www.sahealth.sa.gov.au/samep

Government of South Australia
SA Health

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Outcomes - Nov 2011 – Feb 2018

- 29 reviews (21 medicines, 29 indications)
  - 83% clinician initiated
  - Non previously PBAC review, 6 subsequently
- 48% positive recommendation
  - Most for < 20 patients
  - Level of evidence
    - Systematic review 4/13
    - RCT 6/13
    - Uncontrolled comparative data 1/13
    - Case series 3/13
- 52% negative recommendations
  - Insufficient evidence cf alternatives, limited or uncertain benefits


HEALTH POLICY

CSIRO PUBLISHING

Australian Health Review, 2021, 45, 207–213
https://doi.org/10.1071/AH20018

South Australian Medicines Evaluation Panel in review: providing evidence-based guidance on the use of high-cost medicines in the South Australian public health system

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More recent reviews

- Aug 22-Sept 23
  - 6 full reviews
    - 2 approved, 1 pending
    - 2 not listed but streamlined IPU with outcome assessment in 12months
  - 5 update reviews of existing listings
    - remove requirements for eligibility checklists
  - Rituximab review
  - 2021 – 11 indications plus PBS indications
  - unrestricted but recommend QUM approach

SA Medicine Evaluation Panel (SAMEP) From August 2022- October 20223		
Provide to SAMAC-Date	**Request to SAMEP**	**Recommendation by SAMEP to SAMAC**
SAMAC August 2022	- Thiotepa - conditioning protocol for autologous haematopoietic stem cell transplants in the treatment of CNS lymphoma	to list thiotepa as part of the conditioning protocol for autologous haematopoietic stem cell transplant (ASCT) in the treatment of CNS lymphoma on the statewide high cost medicines formulary.
SAMAC Dec 2022	Rituximab – changes to PBS listing to unrestricted	Noting
SAMAC Feb 2023	Ustekinumab – Hidradenitis suppurativa in patients who have failed multiple treatments including adalimumab	NOT list ustekinumab for hidradenitis suppurativa in patients who have failed multiple treatments including adalimumab (4th or 5th line therapy) on the statewide high cost medicines formulary, but instead to recommend a streamlined IPU with review of the usage and outcomes after one year
SAMAC Feb 2023	Eltrombopag – Thrombocytopenia following allogeneic haematopoietic stem cell transplant	NOT list eltrombopag for thrombocytopenia following allogeneic haematopoietic stem cell transplant on the statewide high cost medicines formulary, but instead to recommend a streamlined IPU with review of the usage and outcomes after one year
SAMAC June 2023	Anagrelide – Essential thrombocytopenia	recommendation to remove the Eligibility Checklist for anagrelide in essential thrombocytopenia and list anagrelide on the SA Medicines Formulary as shown below
SAMAC August 2023	Ustekinumab – ulcerative colitis and Crohn's disease in paediatric patients who become resistant or develop antibodies to anti-TNF medicines	recommendation to list ustekinumab on the SA Medicines Formulary with an Eligibility checklist for paediatric patients (aged 6 years and over) with moderate to severe refractory Crohn's disease, or moderate to severe ulcerative colitis
SAMAC August 2023	Vedolizumab – ulcerative colitis and Crohn's disease in paediatric patients who become resistant or develop antibodies to anti-TNF medicines	recommendation to list vedolizumab on the SA Medicines Formulary with an Eligibility checklist for paediatric patients (aged 6 years and over) with moderate to severe refractory Crohn's disease, or moderate to severe ulcerative colitis
SAMAC August 2023	infliximab – acute severe colitis due to ulcerative colitis, Crohn's disease or inflammatory bowel disease-unspecified	to remove the Eligibility Checklist for infliximab in the treatment of acute and severe inflammatory bowel diseases and list infliximab on the SA Medicines Formulary as: 'acute severe colitis due to ulcerative colitis, Crohn's disease or inflammatory bowel disease-unspecified in patients not responding to intravenous corticosteroids at Day 3 or Day 7 as per Oxford criteria'
SAMAC August 2023	Zoledronic acid – Early breast cancer	to remove the Eligibility Checklist for zoledronic acid in the prevention of recurrence in postmenopausal women with early breast cancer and to amend the listing in the SA Medicines Formulary as shown below:
SAMAC October 2023	Gemtuzumab ozogamicin – de novo CD33-positive acute myeloid leukaemia	to list gemtuzumab ozogamicin on the SA medicines formulary for de novo CD33-positive acute myeloid leukaemia
SAMAC October 2023	Nelarabine – T-Cell leukaemia in the paediatric setting	- to NOT list Nelarabine for T-Cell leukaemia in the paediatric setting on the SA medicines formulary and - to allow access to nelarabine through the IPU process overseen by WCH-DTC in the context of the affiliation of the WCH's Haematology and oncology group with the Children Oncology Group (COG).

- **SAMAC (SA Medicines Advisory Committee)**

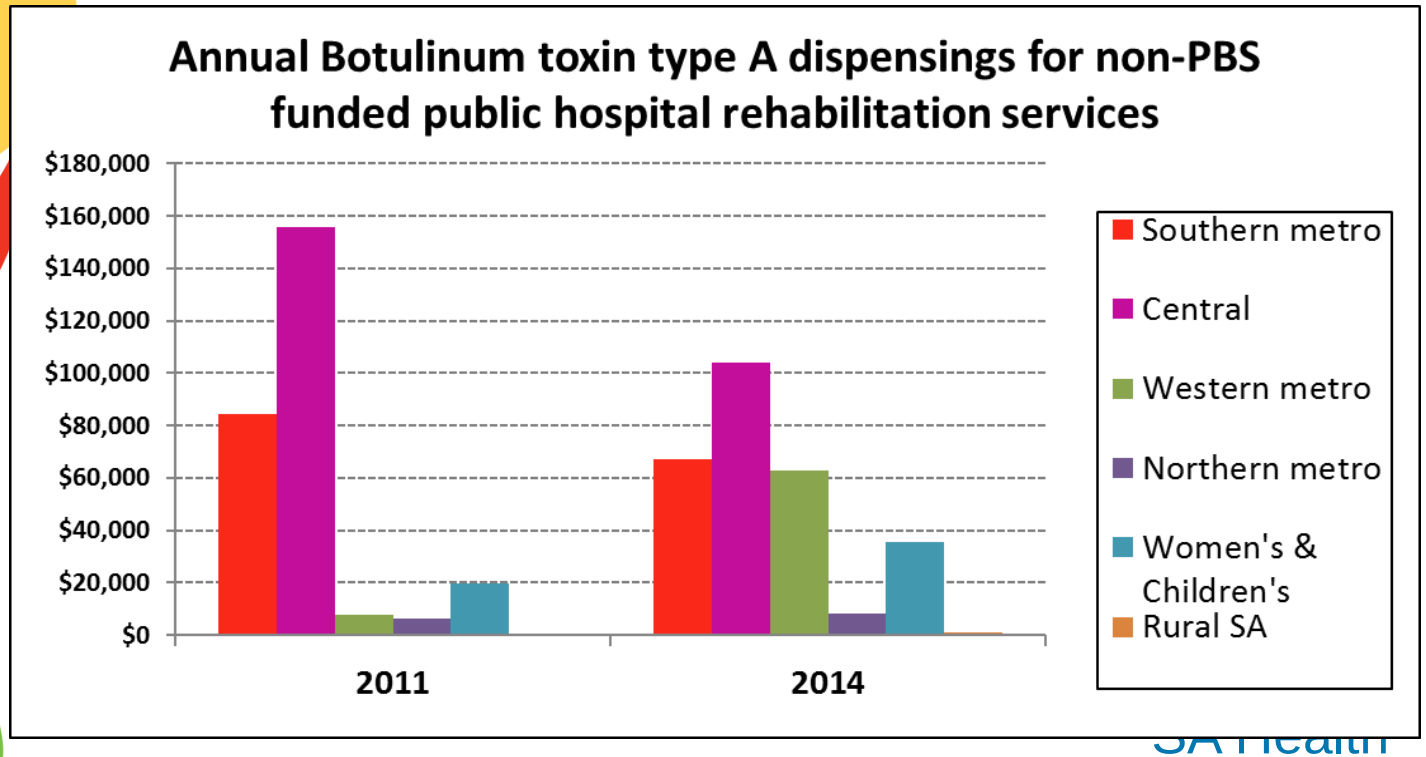
Outcomes

- Refined treatment pathways
  - Evidence or local data informed
  - Refined patient criteria, monitoring, other treatment options, linkage of clinicians with surgeons/other specialities
- Transparent, equitable, accepted
  - Clinicians, budget holders, consumers
- Reviews used as reference for PBAC evaluations

  e.g. rituximab 11 reviews and approved indications, plerixafor for stem cell mobilisation; eligibility criteria for rituximab for ANCA-associated vasculitis
- Savings $1.4m in first few years,
  - costs minimised through refined pathways, price negotiations
- Outcome reviews
  - Inform continued investment, disinvestment

Increasing equity across the state

- Botulinum toxin type A (Botox) - reviewed early 2012 for focal spasticity
- Marked inequity of access across the state noted before SAMEP review
- Little change in overall expenditure, but equity across the state improved:



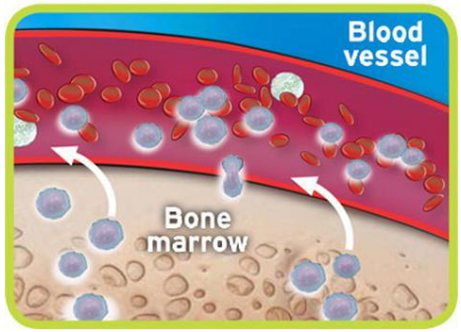
Local outcome data

- Outcome data useful to inform decision-making when:
  - Limited evidence base
  - Refractory disease – no alternative options
  - Off-label / unregistered indications

> IPU data or audit of prior local usage can assist formulary decision making:
>
> - Clinical outcomes
> - Direct costs
> - Indirect costs
> - Outcomes for patients treated with comparator/ no treatment

Local outcome data

- Plerixafor formulary application May 2012
- To mobilise stems cells to peripheral blood for collection and autologous transplantation
- $21K per treatment
- Previously rejected by the PBAC for lymphoma & multiple myeloma patients
- Sept. 2012 → CADTH recommended not listing plerixafor due to uncertainty regarding the most appropriate patient population



Using local outcome data to assist decision making

- 23 patients had received plerixafor
- Expert opinion → some patients would not have mobilised sufficient cells without it, BUT
  - Which patients obtained most benefit?
  - **In which patients would it be cost-effective?**
- Review of local data → 3 groups
  - Patients who would likely mobilise cells without plerixafor
  - Patients who mobilised some cells but not quite enough on first large volume apheresis collection prior to plerixafor
  - Patients who failed to mobilise enough cells despite receiving plerixafor

Local outcome data

- assisted in identifying patient group where benefit could be maximised.
- Led to development of a revised clinical pathway
  - Formulary listed for a more defined population (based on peripheral blood CD34+ cell count), maximum of 2 vials / patient
- Post-hoc analysis of pre-marketing trial data was subsequently published
- Positive recommendation for PBS funding after resubmission to PBAC in Nov 2013

Success factors

- Resources for HTA
- Executive support
- Clinician engagement and leadership
- Very engaged panel members
- Smaller state - collaboration
- Communication and feedback
- Well established - trusted and transparent process
  - Equity and evidenced-based, consistent
- Updates and evaluations
  - Evidence updates, efficient timely processes
  - Feedback lead to changes in cost thresholds

Outcomes

- Updates and evaluations
  - Evidence updates, efficient processes
  - Feedback lead to changes in cost thresholds and exec approval process

High-Cost Medicine

- ≥ $15,000 per patient per treatment course or per year; or
- ≥ $150,000 for an individual hospital per year; or
- ≥ $450,000 within the SA public health system per year.
- LHN and Exec – report 6monthly
- Approval high cost or risk eg >$200k

Challenges

- HTA expertise
- Volume of work
- Cost-effectiveness analysis (ICER)
  - Use existing data / trial data analysis
  - Perspective - Metro/regional, state hospital perspective vs societal perspective
  - Other value considerations
- More difficult choices
  - marginal improvements with high cost/complexity
  - Patient benefit, values
- Evidence challenges
  - Paucity, early adoption, RWE, paediatrics
  - Gene therapy, precision medicine
- Re-structures
- Affordability….

Challenges and opportunities

- Clinician time to develop pathways
  - Pharmacist support
- Outcome assessment
  - Approach, data systems, time
  - Ongoing investment /disinvestment decisions
  - PHD student
- Communications and input to PBAC
  - Shared challenges and collaboration
  - Sharing data and information
  - Cost and pricing
- Commonwealth HTA and other reviews
- Emerging pathways for funding – HSTs

Next steps ?

Opportunities for collaboration

- interstate and national hospitals
- system capacity building
- Co-developed evidence assessment, cost and cost-effectiveness analysis
- Sharing assessments
- CATAG work
- PBAC / Cwlth processes

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