



Kia ora

Your Official Information Act request, reference: GOV-017918

Thank you for your email of 22 April 2022, asking for the following information under the Official Information Act 1982 (the Act):

I would like to request information that explains why ACC chooses to fund the pharmaceutical copayment for its clients. Particularly any insight or explanation behind why clients with approved claims are funded for certain co-payments versus an individual with a chronic condition or illness who is not covered by ACC. I would like to be provided with any reports or investigations from 2011 to present that review or discuss ACC's Pharmaceutical Funding Policy, especially any content that evaluates access to medication, financial barriers, and/or healthcare inequities.

Reports and investigations on ACC's Pharmaceutical Funding Policy

Attached are the following documents:

- Operational Policy Committee: Pharmaceutical (reimbursement) Price Management
- Policy Governance Committee: Scoping paper: Proposal to develop ACC's policy on funding pharmaceuticals
- Operational Policy Paper: Pharmaceuticals policy proposal

Schedule 1, section 3(1)(c) of ACC's legislation sets out that ACC is liable to pay or contribute to the cost of pharmaceuticals. The legislation is publicly available and can be found at www.legislation.govt.nz/act/public/2001/0049/latest/DLM99494.html?src=qs.

Staff names have been removed as per your confirmation on 17 May advising that they are not required.

Your request for information that explains why ACC chooses to fund the pharmaceutical co-payment is not a request for official information

Under the Act a distinction exists between a request for information already known and held by an agency (official information), versus a request for an agency to form an opinion or provide an explanation or comment, and thus create new information to answer a request (not official information).

You have asked us for an explanation/comment which, as outlined above, is not a request for official information. We are not required to respond to such requests under the Act. For further information, we refer you to the Office of the Ombudsman's guide Making official information requests at www.ombudsman.parliament.nz/resources/making-official-information-requests-guide-requesters.

If you're concerned about this response, please get in touch

You can email me at <u>GovernmentServices@acc.co.nz</u>. You can also complain to the Ombudsman via <u>info@ombudsman.parliament.nz</u> or by phoning 0800 802 602. Information about how to make a complaint is available at <u>www.ombudsman.parliament.nz</u>.

Ngā mihi

Sara Freitag Acting Manager Official Information Act Services Government Engagement & Support



Operational Policy Committee Cover Sheet

Agenda item	To be added by the Committee Secretary	Date	16 November 2011
Title	Pharmaceutical (reimbur	sement) Price Man	agement
Outcome sought	 contribute to the contribute to the contribute to the contribute to the contribute to the contribution of the contrib	(reimbursement) P ost of non subsidise nstead of paying pl above policy by cturer's medicines holesale mark up, fee it will pay for n aceuticals ent from The Phar	rice Management policy be to ed and partly subsidised rovider determined costs). price list and pharmacy mark up and onsubsidised and partly macy Guild or pharmacy
Action sought			ion 🗵
Strategic implications	To balance our legislative responsibility to levy pay contribution it should ma	ers, ACC needs a	consistent policy on the
	Issue size		L
	Financial impact (add \$\$ val	ue)	L
	Impact on rehabilitation rate	s/duration	L
SU(C))	Client impact		L
	Provider impact		L
$\langle \rangle \rangle$	Impact on operational staff		L
\mathcal{S}	Public perception impact (+v	e)	L
	Legal impact		L
	ACC-wide support		L

Signature:

Manager

Signature:

National Manager

Operational Policy Committee

Pharmaceutical (reimbursement) Price Management

1 Purpose

- 1.1 This paper is to seek agreement that
 - ACC's Pharmaceutical (reimbursement) Price Management policy be to contribute to the cost of non subsidised and partly subsidised pharmaceuticals and
 - 2. This policy be implemented by
 - creating a manufacturer's medicine price list and
 - determining the manufacturer's wholesale mark up, pharmacy mark up and dispensing service fee it will pay
 - seeking endorsement from The Pharmacy Guild or other pharmacy sector representatives.

2 Recommendations

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- 2.1 In order to provide a sustainable control on pharmaceutical reimbursement expenditure it is recommended that the Operational Policy Committee:
 - a. <u>Agree</u> that the ACC Pharmaceutical (reimbursement) Price Management policy be to contribute to the cost of non subsidised and partly subsidised pharmaceuticals.
 - **b.** <u>Agree</u> to implement the above policy by:
 - creating a manufacturer's medicine price list and
 - determining the wholesale mark up, pharmacy mark up and dispensing service fee ACC will pay
 - iii. seeking endorsement from The Pharmacy Guild or pharmacy sector representatives.
 - c. <u>Note</u> that ACC will continue to work with Pharmac to:
 - i. seek assistance to develop a manufacturer's medicine price list for pharmaceuticals funded by ACC
 - ii. gain clinical effectiveness and cost effectiveness information on medicines
 - iii. discuss opportunities to align funding application processes (eg. exceptional circumstance funding).

3 Current ACC Pharmaceutical Payment Methods

- 3.1 ACC funds the cost of pharmaceuticals used by our clients in community by
 - **Contributing** ~\$10million dollars annually through the Public Health Service Agreement (PHAS)
 - **Paying contract prices** where the cost of pharmaceuticals is included in the service contract price (eg. some residential support service contracts)
 - Reimbursing ~\$3 million annually to clients, pharmacies (and some doctors) for pharmaceutical costs (covering prescription copayment costs for subsidised pharmaceuticals, extra costs for partly subsidised pharmaceuticals and full costs for non subsidised pharmaceuticals)¹
- 3.2 The PHAS pharmaceutical expenditure (\$10 million) is a well controlled fixed component within the PHAS agreement. Note this is the extra payment made for covering the cost of subsidised community pharmaceuticals used by clients. It is an additional amount to attached to the PHAS agreement. This amount has been relatively stable over the last ten years, adjusted for inflation each year).
- 3.3 Contracts which include pharmaceuticals as part of their service pricing are well controlled as part of Health Procurement processes.
- 3.4 The pharmaceutical reimbursement expenditure has no cost management framework in place. ACC continues to pay pharmaceutical prices (PP) which are provider determined.²

4 Problem definition

- 4.1 The majority of ACC pharmaceutical reimbursement expenditure (80%) is for non subsidised and partly subsidised pharmaceuticals and the pharmaceutical cost per claim is increasing.
- 4.2 ACC does not define any component of the reimbursed pharmaceutical price it pays for non subsidised and partly subsidised pharmaceuticals. Prices for these are provider determined.
- 4.3 Currently, the reimbursement pharmaceutical management process relies solely on volume management (ie. clinical entitlement management).

¹ Non subsidised medicines are usually new medicines which have a high manufacturer's price and are not paid for by District Health Boards (DHBs). Partly subsidised medicines are medicines which DHBs only pay for a proportion of the manufacturer's price.

² A pharmaceutical price is made up of the following components:

- The manufacturer's medicine price plus
- A wholesalers mark up plus
- A pharmacy retail mark up plus
- A dispensing service fee plus
- gst

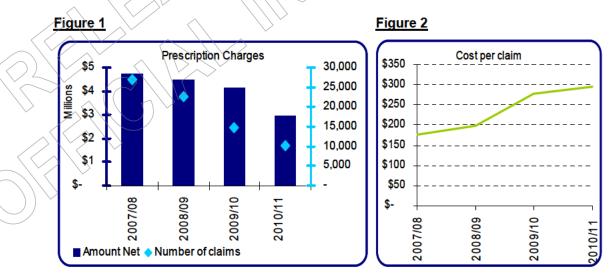
4.4 Lack of a cost management contract, regulation or policy leaves ACC open to provider determined costs – over the long term this can lead to unsustainable cost growth as new medicines continue to enter the market.

5 Size of Problem

- 5.1 Pharmaceutical reimbursement expenditure (\$3million) is controlled through case by case entitlement management and has resulted in a stabilisation and decline of total reimbursed pharmaceutical expenditure.
- 5.2 However reimbursement savings due to lower claims numbers is under pressure because of an increasing cost per claim. The main driver for the increasing cost per claim is the funding of non subsidised and partly subsidised medicines, both new ones coming on to the market and previous ones which clients have been stabilised on.
- 5.3 The following tables and graph show the Prescription Charges expenditure and trends over the last four years.

Financial Year	Expenditure	Number of Claims	Cost	per Claim
2007/08	\$ 4,735,727	26,905	\$	176
2008/09	\$ 4,487,512	22,560	\$	199
2009/10	\$ 4,132,859	14,864	\$	278
2010/11	\$ 2,978,973	10,064	\$	296

Table 1 – Prescription Charges – Pharmaceutical (Reimbursement) Expenditure



- 5.4 Non subsidised/partly subsidised pharmaceuticals make up ~80% (~\$2.4million) of ACC's reimbursed pharmaceutical expenditure. The balance of reimbursements is for co payments on subsidised pharmaceuticals, ie. \$3 \$15 reimbursement requests.
- 5.5 The top non subsidised pharmaceuticals where ACC pays provider determined prices include pregabalin, Cox2 inhibitors, erectile dysfunction products, opiate analgesics

and 'other': together these made up 50% of total pharmaceutical expenditure in the year ending July 2011 (\$1.4million/\$2.7million).

5.6 Another non subsidised pharmaceutical, pemetrexed (an oncology drug,) made up 20% of expenditure in the ending July 2011 – however ACC has controlled the price paid for this by limiting it to manufacturer price only.

6 Pharmaceutical (reimbursement) Price Management – The Pharmaceutical Management Agency (Pharmac), District Health Boards and ACC

- 6.1 The Pharmaceutical Schedule is a manufacturer's medicine price list that Pharmac has negotiated on behalf of DHBs. Pharmaceuticals not on this list are 'not subsidised' by DHBs.
- 6.2 A national pharmacy services agreement exists between DHBs and community pharmacies which defines the wholesaler/ pharmacy mark up and dispensing service fee that the DHBs pay towards a subsidised PP.
- 6.3 The Pharmaceutical Schedule and DHB pharmacy services agreement manages ACC risk for its pharmaceutical expenditure covered by the PHAS agreement, however there is no manufacturer's medicines price list or pharmacy service agreement that manages ACC risk for partly subisidised and non subsidised pharmaceutical expenditure.
- 6.4 ACC legislation does not limit ACC pharmaceutical funding to only those items listed on The Pharmaceutical Schedule. ACC legislation requires ACC to contribute to the cost price of any pharmaceutical that is reasonably required to facilitate treatment.³.

7 Working with Pharmac, DHBNZ and the Ministry of Health (MoH)

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- ACC has regularly approached Pharmac seeking assistance with non subsidised Pharmaceutical (reimbursement) Price Management: requesting Pharmac to either create an ACC manufacturer's medicine price list or allow ACC to use their existing 'exceptional circumstances' pricing mechanism to manage costs for ACC partly subsidised and non subsidised pharmaceutical expenditure. To date, Pharmac have been unable to assist.
- ACC has also approached DHBNZ to discuss how the current Pharmacy Services agreement may be used as a benchmark agreement by ACC to manage costs for partly subsidised and non subsidised pharmaceuticals. They have advised that ACC needs to determine its own reimbursement price as it cannot include ACC as a third party to the contract.
- 7.3 ACC has approached the Ministry of Health to request integration of ACC prescription identifiers into the current pharmacy payments systems through Sector Support. They have advised that although this may be possible, ACC will need to determine its own price contribution.

³ Accident Compensation Act, 2001, Schedule 1, Clause 3(1) (c) – *The Corporation is liable to pay or contribute to the cost of any service if the service facilitates the treatment and the service is reasonably required as an ancillary service related to treatment, such as pharmaceuticals prescribed by a treatment provider who has statutory authority to prescribe pharmaceuticals.*

7.4 Pharmac has recently advised ACC that they may be able to assist with developing a price list for medicines funded by ACC and explore the development of a central 'named patient' pharmaceutical funding process for non subsidised medicines. But they advise it is up to ACC to determine the wholesale/pharmacy mark up, and dispensing fee that ACC will pay for these medicines.

8 Proposal for a strengthened operational approach to manage pharmaceutical price

- 8.1 To better manage the current pharmaceutical reimbursement expenditure and achieve sustainability of future reimbursement expenditure, it is proposed that ACC introduce a Pharmaceutical (reimbursement) Price Management policy to contribute to PP for partly subsidised and non subsidised pharmaceuticals, instead of paying provider determined costs.
- 8.2 To implement a price contribution policy a pharmaceutical price calculation tool will be needed which contains the:
 - Manufacturer's medicine price determined by ACC with assistance from Pharmac
 - Wholesalers mark up contribution determined by ACC
 - Pharmacy mark up contribution determined by ACC
 - Dispensing fee contribution determined by ACC
 - Goods and Services tax standard rate.

8.6

- 8.3 The above tool would need to be developed with input from The Pharmacy Guild or other pharmacy sector representatives who could inform ACC procurement process and endorse implementation.
- 8.4 Implementation of a Pharmaceutical (reimbursement) Price Management policy would be gradually rolled out, with a focus to control the top five expenditure items: pregabalin, Cox2 inhibitors, opiate analgesics and 'other' for new funding approvals. (Price contributions for erectile dysfunction products are already listed in Informe).
- 8.5 The current process to reimburse 'first only' reimbursement requests from clients would continue to be in place (this ensures that reimbursement requests for pharmaceuticals dispensed close to an injury date and for a limited dollar value are reimbursed).
 - A price contribution process is currently being used by clinical advisors (pharmaceuticals) – through use of an excel sheet which defines the components of a PP and calculates a final PP eg for pregabalin and tramadol.
- 8.7 However, a price contribution process is not able to be effectively implemented by all client services staff because operational policy is silent on what amount should be reimbursed and there is no central pharmaceutical price calculation tool.
- 8.8 An example, using pregabalin, of how a price contribution policy can impact on pharmaceutical reimbursement expenditure is given below.

Example 1 – Pharmaceutical (reimbursement) Price Management – Pregabalin (used for pain management)

This example shows how changing the reimbursement amount can decrease the cost ACC pays.

Pregabalin makes up approximately 9% of total pharmaceutical expenditure. (As shown below, it is the fastest rising expenditure within the pharmaceutical budget).

Table 2 - Pregabalin Expenditure

Financial Year	Amount Net	Number of claims	Cost per claim	% of Prescription charges spend	
2008/09	\$33,074	43	\$769	1%	
2009/10	\$139,617	107	\$1,305	3%	
2010/11	\$273,868	208	\$1,317	9%	<

Table 3 - Examples of Pharmaceutical Pricing for pregabalin

Assume daily dose of pregabalin 300 mg daily

Monthly quantity dispensed = 30

Manufacturer's Medicine price = \$89.00

Pharmaceutical Price = (manufacturer price + wholesale mark up + pharmacy mark up + dispensing fee) + gst

	Based on DHBNZ pharmacy service contract for non subsidised medicines	Based on current pharmacy behaviour	Proposed ACC rates
Wholesalers mark up	5%	10%	10%
Pharmacy mark up		60%	20%
Dispensing fee	\$7.70	\$10	\$5.13 **
Gst	15%	15%	15%
Pharmaceutical price	\$116.32	\$191.63	\$141.00

**standard dispensing rate from DHBNZ community pharmacy service contract

Analysis

9.1

This approach is designed to result in:

- Minimal disruption for most clients: Clients will still be able to access the pharmaceutical they need, from the provider and pharmacy of their choice.
 Clients currently pay no copayment for pharmaceuticals and the Pharmaceutical (reimbursement) Price Management proposal should contribute a reasonable price to pharmacies. This should minimise copayments being charged to clients. The current cost contribution trial has not resulted in co payments being charged to clients.
- Being attractive to pharmacists: The proposal sets a clear contribution base and avoids the conflict surrounding the national pharmacy services contract where pharmacists are concerned about current contract mark ups not covering wholesaler margins. It limits dispensing fee to the 'basic' dispensing fee within the DHBNZ contract but recognises that most business practices will mark up their products to cover business costs. The exact mark-up percentages will need to be determined by Health Procurement using The Pharmacy Guild or

other pharmacy sector representatives to inform acceptable wholesaler and pharmacy margins and service fees.

- Cost-effectiveness for levy payers: Implementing a 'fair and reasonable' pharmaceutical price contribution approach is cost effective for levy payers. It will ensure cost management is in place and allow ACC to continue to fund innovative medicines which meet the entitlement criteria of the ACC legislation.
- A consistent administrative approach for ACC: The proposal provides a consistent approach to Pharmaceutical (reimbursement) Price Management. This approach has currently worked on an ad hoc basis, but, with only some case managers and clinical advisors able to determine pharmaceutical price. The current situation leaves ACC open to provider determined pricing there are many examples where this has been exorbitant. Implementation of this proposal will allow all staff to have support and access to a central policy and price list which will allows them to calculate appropriate prices based on dose and quantity.
- Legal defensibility: ACC continues to meet its obligation to pay or contribute to treatment/rehabilitation received by clients. ACC will also be taking a reasonable approach, to fulfilling the legislative requirement to pay for ancillary services. Previous legal advice (LEG 10090) has confirmed that ACC is able to contribute to pharmaceutical prices if done on a reasonable basis.
- Compliance with International labour Organisation Convention 17: New Zealand has ratified this convention, however the 12 October 2010 Cabinet Social Policy Memo (Decision of the Chair) notes that New Zealand is substantially compliant and that New Zealand maintain the current status quo. This proposed policy will not adversely effect current New Zealand status quo and is aimed at managing market mark ups, not manufacturer's price which ACC will usually pay.
- Graduated implementation: to minimise impact on client services staff and health procurement, the initial implementation will centre on determining and controlling reimbursements for the top five pharmaceutical groups for funding approvals, as they become due. There is no intent to suddenly change all current funding approvals. As part of the normal procurement process, the pharmacy sector will be consulted to seek their input and endorsement of the PP tool as it is developed.

10 Key Risks

10.1 Risks with the proposal and mitigation strategies:

Risk	Likelihood	Consequence	Mitigation
Providers challenge legal basis for applying cost contribution	Medium/High	Medium / High	 This process is already being used for some high cost pharmaceuticals – some pharmacies have complained about the contribution cap. Dialogue will need to continue with the pharmacy sector about 'what is reasonable'. The Pharmacy Guild has already advised ACC that it is willing to discuss non subsidised pharmaceutical pricing. However most pharmacies have understood the need to determine a reasonable price contribution and would like clarity about what ACC is willing to pay Information to be provided to sector liaison groups, consumer outlook group and ACC News to advise components of Pharmaceutical (reimbursement) Price Management LEG10090 confirms that ACC may contribute to cost on a 'reasonable' basis
Clients challenge restricted contributions because they have to pay co payment	Low	Low	 Acceptable risk that can be monitored via co payment survey Clients advised by letter about the cost that ACC will pay ACC currently reimburses the first reimbursement request from a client using the 'first only' criteria (ie. close to injury date and low dollar reimbursement request). This will continue if the new policy is implemented. It is only the ongoing funding approvals which will have a cost contribution specified Manufacturer's prices will be paid for all pharmaceuticals – the amount to be controlled will be market mark-ups The current cost contribution trial has not resulted in any copayments being

Risk	Likelihood	Consequence	Mitigation
Client services staff may not implement pharmaceutical price contribution policy	Medium	High	 Develop Excel or other similar tool which allows client services staff to calculate pharmaceutical price and input into client approval letters Pharmaceutical teams to use similar price when generating direct billing agreements with pharmacies The Pharmacy Guild or other pharmacy sector representatives endorsement for the policy will be sought as part of the procurement process

11 Discarded options

- 11.1 Other options to manage pharmaceutical price include:
 - Development of an ACC pharmacy services contract:
 - Discarded because it would be difficult to negotiate and manage a contract for 700 community pharmacies, would involve sector negotiation which might compromise the DHBNZ service contract (they currently spend \$600 million on community pharmaceuticals) and because there is no underlying ACC medicines price list.
 - Development of a 'preferred pharmacy' supplier contract/s:
 - Discarded because both doctors and pharmacists have advised that it is clinically safer to have a local pharmacy dispense pharmaceuticals because it enhances close links between local doctors and pharmacies
 - Note this may change with the advent of electronic prescriptions or if local pharmacies do not accept ACC's cost contribution– however an underlying ACC medicine price list will still be needed to enable this option in future.
 - Do not fund non subsidised or partly subsidised pharmaceuticals:
 - Discarded because ACC legislation does not allow restriction of pharmaceutical funding to those items listed on The Pharmaceutical Schedule.
 - Continue with status quo no Pharmaceutical (reimbursement) Price Management:
 - Discarded because, as illustrated by the pregabalin example, entitlement management does not manage cost/claim. As illustrated by the pemetrexed example (under Financial Implications), managing the price will limit exposure to provider determined high cost pharmaceutical prices where there is a valid entitlement.

12 Financial implications

- 12.1 If a Pharmaceutical (reimbursement) Price Management policy is implemented, there is a potential to decrease the current pharmaceutical reimbursement expenditure.
- 12.2 More importantly, it will provide a ceiling formula for all future pharmaceutical reimbursement expenditure and future proof pharmaceutical reimbursement expenditure.

12.3 An example showing how current price management for pemetrexed has enabled cost saving is shown below.

Example Two – Pharmaceutical Price Management – Pemetrexed (chemotherapy for mesothelioma)

This example shows how implementing a price contribution policy has helped to minimise the cost that ACC may potentially have paid for pemetrexed.

Pemetrexed is approximately 20% of total pharmaceutical expenditure. Although high in actual costs, its cost/claim growth has been managed because the price paid by ACC has been limited to medicine price and gst only, as shown by the following table.

Financial Year	Amount Net	Number of claims	Cost per claim	% of Prescription charges spend
2007/08	\$608,283	37	\$16,440	13%
2008/09	\$404,227	30	\$13,474	9%
2009/10	\$562,268	39	\$14,417	14%
2010/11	\$654,693	40	\$16,367	22%

Table 4 – Pemetrexed Expenditure

Table 5 - Examples of Pharmaceutical Pricing for pemetrexed

Manufacturer's Medicine Price = \$2353.05 per vial

Note – this is a hospital pharmaceutical and not used in community.

CV	Based on current hospital pharmacy behaviour	Actual ACC rates
Wholesalers mark up	10%	-
Hospital Pharmacy mark	30%	-
Dispensing fee	\$50	-
gst	15%	15%
Pharmaceutical price	\$3927.09 per vial	\$2706.00 per vial

 Table 6 - Cost savings for pemetrexed because of price control – Based on 2010/11 data

Total Actual Expenditure (ACC determined price)	Actual Cost per claim (ACC determined price)	Number of claims	Number of vials used per claim	Potential Cost per claim (hospital determined price)	Total Potential Expenditure (hospital determined pricing)
\$654,693	\$16,367	40	\$16367/\$2706) = 6	\$3927.09 x 6 = \$23,562.36	\$23,562.36 x 40 = \$942,4944.40

13 Implementation

13.1 Implementation will be led by Clinical Services with support from Claims Management Health Procurement Support and Claims Processing Specialist Services (CPSS). If the policy is agreed to, the following will steps need to be taken:

- a. Claims Management Health Procurement Support (CMHPS) will need to seek a provider of manufacturer's medicine prices ACC currently has an agreement with Propharma for medical consumable prices and supply and Pharmac has offered their assistance to advise competitive medicine prices for ACC listing. Alternatively, pharmaceutical companies can advise what their ex manufacturer's cost is.
- b. CMHPS will need to determine and advise a reasonable wholesaler, pharmacy mark up and dispensing fee that ACC should pay. This will be done by looking at current pharmacy sector information and discussions with The Pharmacy Guild or other pharmacy sector representatives.
- c. Based on the above, a pharmaceutical price list calculation tool will need to be developed and published on Informe or other central repository for staff to access. The Pharmaceutical Advisor has created a draft excel spreadsheet which can be fine tuned for this purpose.
- d. CMHPS will need to review the prices of the medicine price list every quarter and review the mark ups and dispensing fees every year. Initially the medicine price list can consist of the top five to ten high cost pharmaceuticals that ACC reimburses. New items can be added to the list each quarter as pricing information becomes known or if new pharmaceuticals enter the market which ACC must fund. The current pharmaceutical excel sheet contains five products already.
- e. Claims management staff will need to specify cost contributions for ongoing pharmaceutical funding approvals. This is already part of the current funding approval process, but not well done due to the lack of a central price guidance tool.
- f. CPSS will ensure the direct pharmacy billing letters specify cost contributions and 'first only' reimbursements as they currently do
- g. Internal communication: Clinical Services will update pharmaceutical policy and process with the new Pharmaceutical (reimbursement) Price Management policy and tool and inform Claims management and health procurement staff through their management lines and via a Noticeboard item about the new policy and its implementation. Training on the use of a PP tool will be led by Clinical Services.
 - External communications: Clinical Services will communicate the general change in approach to provider groups, sector liaison groups, consumer outlook groups and via ACC News.
 - Review and monitoring: Clinical Services, along with Health Procurement Support will review the approach on an ongoing basis, monitor any expenditure changes and deal with any anecdotal concerns from providers, professional bodies and clients as appropriate.

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14 Consultation

Summary of views

Stakeholder/Team	Comment	Action taken
Out of Scope Policy Manager	Clarifications needed in paper around implementation and probability of success.	Implementation tactics clarified. Success probability illustrated through two examples in paper showing the impact of current price control (pemetrexed) and new price control (pregabalin)
Out of Scope National Manager, Claims Processing and Specialist Services	I am comfortable with the proposed approach. Care would need to be taken to ensure that implementation of this initiative does not detract from other initiatives with a higher payback. I am uncertain as to the staffing impact of this approach.	
Out of Scope National Manager, Claims Management Network	Feedback as per outcome of the Claims Management Executive meeting below. Comfortable with approach being limited and gradual	
Out of Scope Chief Risk Officer	No feedback	
Out of Scope	Minor corrections. As previously advised, there is no guidance in the Act or any regulation as to when ACC must "pay the cost" as against "contribute to the cost", and it is prudent for ACC to be able to base its decision on 'reasonableness' where it decides not to pay (all) the cost of a pharmaceutical that has been prescribed in accordance with 3(1)(c). That requires any proposed policy, such as	Minor corrections made Feedback noted
	that in your paper, to be 'reasonable' and one that is justifiable on a 'reasonable' basis. In my view, your paper achieves that. As a buyer in the market for pharmaceuticals, ACC is free to secure pharmaceuticals on the basis of prices that it is prepared to pay rather than prices that the vendor fixes, if ACC has the commercial clout to obtain on that basis for its clients those pharmaceuticals for the cost of which it is liable to pay or contribute.	
	As you are aware, ACC does not have the exemption from the operation of the Commerce Act that PHARMAC and the DHBs do have. This means that, in obtaining pricing information in conjunction with either PHARMAC or a DHB and in settling the prices ACC is prepared to pay, ACC will need to <u>ensure that it can demonstrate</u> that it does	

Stakeholder/Team	Comment	Action taken
	not effectively participate in any contract or arrangement or arrrive at an understanding with any of those entities, that has the intention <u>or effect</u> of fixing any price of any pharmaceutical or substantially reducing competition in the market for its sale. <u>Commercially</u> , ACC runs a risk that pharmacies may refuse to provide to clients prescribed pharmaceuticals at the prices ACC determines it will pay using the methodology outlined in the paper in paragraphs 22 and 23. In paragraphs 29 and 30, you express optimism that this refusal is unlikely to occur - the success and legal defensibility of the	
Out of Scope Director, Clinical	policy in practice will rest on that. Signed off for internal consultation	
Services Out of Scope Manager, Pricing and Marketing Analysis	 It would be good to know ACC's pharmaceutical cost growth via PHAS (expenditure figures are only limited to contracts and reimbursements) It would be good to weigh up (calculate) the pros and cons of the reimbursement (currently on a fee for service basis) model versus contracting to figure out the optimal expenditure levels. Another option outside the status quo is to outsource all pharmaceutical procurement to experts like Pharmac. ACC provides Pharmac with an ACC schedule to ensure good results (i.e. "negotiated" prices plus clinical outcomes supported by evidence-based studies). Overtime, I understand Pharmac will be taking over the responsibility of pharmaceutical purchases for DHBs so it would be worth investigating this option down the track. I think the Pharmaceutical market is a pretty complex space which is why I would rely on world class entities like Pharmac to do our bidding. May be something to consider down the track. 	 PHAS expenditure growth for community pharmaceuticals included. With the current negotiations continuing between DHBNZ and the pharmacy sector on contracts, it would not be useful for ACC to develop a competing contract with differing conditions to that of DHBNZ. This may happen in the future if we purchase specific services, other than dispensing, but the current focus is to manage price paid for reimbursements in a way which does not compromise Health's position. Future contract developments would need to occur if the current PHAS contribution of \$10million was changed. Pharmac has an exemption from the Commerce Act and its actions are focussed on manufacturer price controls. They only advise DHBNZ re supply mark ups Although ACC may seek advice from them, we can not use their price control mechanisms. The focus of this paper is mark up determination, not manufacturer price control.
Out of Scope Manager, Health Procurement Support	Concerns re the expertise and resource that might be needed to implement the policy	Discussed current information on hand from pharmacy sector and potential use of current supplier of Medical

Stakeholder/Team	Comment	Action taken
		manage a manufacturer's price list. Agreed that implementation could be gradual, starting with the five to ten highest cost medicines to minimise resource impact on the Health Procurement Support team. Agreed that focus would not be to negotiate manufacturer's price, but to determine the mark-ups that ACC was willing to pay using existing pharmacy sector and DHBNZ contract information.
Out of Scope Manager, Treatment Programs	Clarification on phrase 'contribute to cost' and concerns re the expertise and resource that might be needed to implement the policy	Paper clarified. Discussed current information on hand from pharmacy sector and potential use of current supplier of Medical Consumables (Propharma) to manage a manufacturer's price list. Agreed that implementation could be gradual, starting with the five to ten highest cost medicines to minimise resource impact on the Health Procurement Support team
Claims Management Executive	Concerns raised that payments staff may need to argue with individual pharmacies about pricing contribution. Concerns raised about how much this might impact on staff	Implementation to include seeking agreement/endorsement of The Pharmacy Guild or pharmacy sector representatives of the pricing contribution policy – added to paper
		focussing on high expenditure items with training support in place for client services managers - added to paper

Committee quality rating for this paper

To be completed by Committee consensus:

	Not fit for purpose				Fit for purpose
Quality of Advice	1	2	3	4	5
Readability/Flow	1	2	3	4	5
Consultation	1	2	3	4	5
Overall rating	1	2	3	4	5
Reasons for this rating					

Policy Governance Committee

Title	Scoping paper: Proposal to develop ACC's policy on funding pharmaceuticals
Status	Decision 🖂 Information 🗌 Consideration 🗌
Meeting Date	16 December 2020
Agenda Item	[completed by Executive Coordinator]

1 Purpose

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2.1

- 1.1 This paper asks that the Policy Governance Committee (PGC) agree to work being undertaken to develop ACC's pharmaceutical policy. The proposed project will clearly establish ACC's position on funding pharmaceuticals for clients where the pharmaceutical has been prescribed by a health practitioner with statutory prescribing rights.
- 1.2 To ensure the policy is developed on a principled basis, we have established a set of 'guiding principles' to inform the policy. We seek agreement on these principles from PGC.
- 1.3 If PGC agrees, we will present the final policy for endorsement in early 2021.

Recommendations

We recommend that the Policy Governance Committee (PGC):

- (a) Note that ACC assesses requests for pharmaceuticals as an entitlement for clients on a case-by-case basis, where it is deemed "practicable" for the purposes of a client's recovery.
- (b) **Note** that there are a number of current issues that mean we do not clearly and consistently guide decision making and that decision making is unnecessarily burdensome.
- (c) Note that there are other agencies involved in the process of making pharmaceuticals accessible, including PHARMAC, Medsafe, and prescribing and dispensing health practitioners.

- (d) Note that ACC's role as a funder is not clearly articulated, but it can operate on a 'high trust' model with providers whereby ACC defers clinical expertise to health practitioners rather than making its own assessment that a treatment is practicable.
- (e) **Agree** to Operational Policy leading a work programme to redevelop ACC's pharmaceutical policy and presenting this policy to PGC in early 2021.
- (f) Agree that the policy development should be guided by the following principles. ACC's approach should:
 - i. be legally compliant;
 - ii. ensure consistent pharmaceutical decision-making, and be consistent with the way that ACC makes about decisions in other domains;
 - iii. restore maximal rehabilitation and health outcomes for clients;
 - iv. reduce ACC's active claims management to the extent possible; and
 - v. maintain ACC's responsible stewardship of scheme costs and boundaries.

3 Strategic alignment

3.1

Access to pharmaceuticals impacts customer outcomes and experience, as well as ACC's financial sustainability of the scheme and boundaries. There are also known equity issues relating to pharmaceuticals, particularly for Māori who access medicines at lower rates than non-Māori despite their higher health care needs.¹ Responding to better customer outcomes for Māori is embedded in Whāia Te Tika.

Background

- Under ACC legislation, pharmaceuticals and other medical consumables are an entitlement that clients with a covered injury may be eligible to receive.
- 4.2 Schedule 1 of the Accident Compensation Act 2001 (the Act) defines the conditions under which ACC is liable to pay for the cost of pharmaceuticals as a treatment.² Under clause 2, ACC "is liable to pay the cost of the claimant's treatment if the

¹ Achieving medicine access equity in Aotearoa New Zealand (PHARMAC, 2020).

² ACC may also fund pharmaceuticals as an ancillary service related to treatment (Sechedule 1, clause 3 of the Act).

treatment is for the purpose of restoring the claimant's health to the maximum extent practicable" as long as the treatment is considered:

- (a) necessary and appropriate;
- (b) of the quality required for its purpose;
- (c) performed only on the number of occasions necessary for that purpose; and
- (d) is provided by a treatment provider of a type who is qualified to provide that treatment and who normally provides that treatment.
- 4.3 Therefore, where a pharmaceutical is prescribed to treat a covered injury, and the pharmaceutical is within the health practitioner's scope of practice to prescribe, ACC needs to determine whether it is 'practicable' to fund it. In relation to rehabilitation, "practicable" takes into account a number of considerations including, cost and cost effectiveness, client rehabilitation outcomes and wellbeing, the nature and consequences of the injury, and the availability of other forms of rehabilitation, among other things.
- 4.4 ACC currently considers requests for pharmaceuticals on a case-by-case basis Where ACC approves a funding request, it then pays either a small co-payment for subsidised pharmaceuticals (to cover the prescription cost), extra costs for partially subsidised pharmaceuticals, or the full costs for non-subsidised pharmaceuticals.
- 4.5 ACC's pharmaceutical expenditure has steadily reduced over the past five years. In FY15/16, ACC's total pharmaceutical spend was approximately \$4.5 million, whereas in FY19/20 it was approximately \$1.3 million. This is likely due to increased government subsidisation and reduced manufacturing costs.³ PHARMAC's budget increase is discussed in the next section.

The wider health systems roles in pharmaceuticals

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Within the New Zealand health system, there are a number of agencies with responsibilities in this area. Medicines New Zealand is an industry association, set up by the Ministry of Health, tasked with providing a strategic framework to support sound pharmaceutical decision making. Its strategic framework defines three main outcomes for the system:

³ Both the number of claims that were paid pharmaceutical costs and the costs per claim have reduced over this period and contributed to ACC's reduced spend, however, the biggest driver is the reduced cost per claim. This has reduced from an average of \$389 per claim to \$101 over the past five years.

- Access: New Zealanders have access to the medicines they need, including equity of access to medicines.
- Optimal use: medicines are used to their best effect.
- Quality: medicines that are safe and effective.
- 4.7 To achieve these outcomes, at a population level PHARMAC's work focuses on access and optimal use of medicines, while quality is primarily the role of Medsafe. At an individual level, health practitioners consider whether to prescribe and dispense the medicines in a specific instance using their clinical judgement to determine that a pharmaceutical is an appropriate and effective treatment in that instance.

Population level funding and regulation

- 4.8 PHARMAC decides which medicines are funded (fully or partially) in order to achieve the best health outcomes from within the available funding. PHARMAC has a fixed annual budget to spend in the most cost-effective way (currently sitting at just over \$1 billion for financial year 2020/2021). This amount has been significantly increased for the next four years following the last Government's Budget announcements earlier this year.⁴
- 4.9 To make the best decisions within its budget, PHARMAC uses a robust decision-making process and relies heavily on experienced doctors and medical staff to look at how effective different medicines are across different medical conditions.
 PHARMAC usually consider a medicine or device for subsidy only after it has been approved by Medsafe.⁵
 - 4.10 Medsafe (a business unit of the Ministry of Health) decides which pharmaceuticals are safe and effective for New Zealanders to use and that these medicines or devices have undergone quality manufacturing processes (often called 'medicines regulation').

⁴ The Government has allocated an additional \$160 million to PHARMAC's budget for the next four years. This does not include an additional \$35 million that was added for essential medicines as part of the Government's response to COVID-19.

⁵ There can be good reasons for departing from usual practice and fund pharmaceuticals that are not Medsafe approved, but this is very rare.

ACC's role in funding pharmaceuticals

- 4.11 ACC operates at an individual level (like prescribing health practitioners). It may be requested to fund prescribed pharmaceuticals related to a client's covered injury by the prescribing health practitioner (using form ACC1171). Often this request is for reimbursement of pharmaceutical costs, because a client will have already paid for the prescription and dispensing of the medicine.
- 4.12 Decisions made by ACC around whether or not to fund pharmaceuticals are distinct from the decisions of prescribers to provide access to pharmaceuticals. A claimant may be prescribed a drug by their treating doctor in relation to a covered injury, which ACC is not liable to fund.
- 4.13 This is because ACC takes into account a number of factors when deciding whether it is liable to fund treatment (i.e. treatment is 'practicable'), including:
 - (a) the nature and severity of the injury;
 - (b) the generally accepted means of treatment for such an injury in New Zealand;
 - (c) the other options available in New Zealand for the treatment of such an injury; and
 - (d) the cost in New Zealand of the generally accepted means of treatment and of the other options, compared with the benefit that the claimant is likely to receive from the treatment.⁶

Decisions made by ACC are also distinct from whether a pharmaceutical is regulated by Medsafe. While Medsafe provides assurance that a pharmaceutical is of a quality standard, there can be other (international) jurisdictions that have a more current assessment of a pharmaceutical's quality. This is particularly true for chemotherapy drugs that are frequently introduced and used before Medsafe can assess them.

However, ACC needs to be mindful that it does not act as a pseudo-regulator and cause undue stress to clients recovering from injuries. In particular, because ACC clients are usually seeking the reimbursement of surcharges for their medicines, ACC's ability to prevent 'harm' to a client from a medicine is relatively limited.

4.16 Therefore, ACC's role is mostly focussed on determining whether a client has cover rather than an assessment of a client's clinical needs and treatment requirements (once cover is determined). ACC then has the option to operate on a 'high trust'

4.14

⁶ Accident Compensation Act 2001; Schedule 1(2)

model with providers whereby ACC trusts that a provider is taking into account the factors that would make a treatment practicable (rather than ACC applying its own assessment of 'practicable').

5 Issues with ACC's current policies

5.1 ACC's current policies do not clearly guide decision making on pharmaceutical requests within ACC's legislative boundaries.

Operational burden

- 5.2 Because ACC is not required to accept the opinion of a treating practitioner (i.e. accept that every prescription is practicable to fund), nor is there any criteria to only fund regulated or subsidised pharmaceuticals, the current policy has an over-reliance on internal clinical assessment of individual requests. This is because ACC does not operate on a 'high trust' model with providers in this space, which is contrary to our strategic direction.
- 5.3 This is operationally burdensome. ACC cannot investigate every request. In 2018, to align with the implementation of MyACC, it was decided that prescriptions under \$18 (i.e. subsidised pharmaceuticals) would be reimbursed to the client without assessment to reduce operating costs and because the risks (to a client's health and to ACC's financial state) associated with subsidised pharmaceuticals were deemed to be very low.⁷ This is not captured in current policy.

Clarity and ease of policy

With the move to Next Generation Case Management (NGCM), there is a requirement that the current polices are clear and accessible. Currently there are many policy and process pages (across Promapp and CHIPs) that a Recovery Team member needs to work through when considering a pharmaceutical request (all the pages are outlined in **Appendix 1** for reference). The relationship between the different pages is particularly difficult to navigate.

⁷ Pharmaceutical's that are \$18 or under are subsidised (generally \$5 or \$15 when specialist prescribed). The \$18 value is due to any potential dispensing costs that are added to the subsidised cost. Both MyACC and paper requests follow this process.

- 5.5 As new pharmaceuticals become available, ACC has often created drug specific policies and processes. However, this is unsustainable as it creates more and more pages to consider.
- 5.6 Moreover, the language used on these pages is not accessible to Recovery Team members outside pharmaceutical expertise.

ACC's role

- 5.7 ACC's role in relation to other agencies is not clearly articulated or captured in the policies. Instead, ACC often re-evaluates clinical appropriateness where this has been established by a prescribing doctor. Where ACC then disagrees with a clinical opinion and the decision goes to review, reviewers will often defer to the expertise of an external specialist (e.g. oncologists for the prescription of cancer drugs) and overturn ACC's decision.
- 5.8 This is because ACC does not clearly establish why its position should be preferred over that of the prescribing specialist or have clear principles to show how the evidence was weighed.

6 Proposal

6.1

6.2

6.3

We propose to undertake a project to analyse and redevelop ACC's position on pharmaceuticals. In doing so we will consider all current policies, processes, and forms associated with pharmaceutical funding (listed in **Appendix 1**). This includes making changes to the ACC1171 'Request for pharmaceutical funding' form, if appropriate.

Out of scope of this project are other medical consumables, Public Health Acute Services funding, and fertility treatment (which is set out in a separate policy).

The intent of the project is to produce a single policy document, that is:

- a) Clear and accessible;
- b) Indicates what requests can be automatically approved;
- c) Indicates when internal clinical advice is required (and where it is not required) before a request can be approved;
- d) Articulates ACC's role in relation to PHARMAC, Medsafe, prescribing health practitioners, and other jurisdictions;

- e) Looks for opportunities to reduce inequities to pharmaceutical access;
- f) Indicates what the flow on effects to ACC's processes and relevant forms should be.
- 6.4 We will also look at how introducing business rules may help us reach these aims, with the help of the Enterprise Business Rules (EBR) team.
- 6.5 Our proposal will include consideration of a number of options for ACC's position on funding pharmaceuticals, including options that take a 'high trust' model to providers. To determine the best option, we will undertake a detailed analysis and risks assessment of the options.

Policy principles

- 6.6 To guide policy development and assessment, we propose that the following guiding principles are used to inform ACC's approach. ACC's approach should:
 - be legally compliant;
 - ensure consistent pharmaceutical decision-making, and be consistent with the way that ACC makes about decisions in other domains;
 - restore maximal rehabilitation and health outcomes for clients;
 - reduce ACC's active claims management to the extent possible; and
 - maintain ACC's responsible stewardship of scheme costs and boundaries.

If PGC agrees that these are the right principles to guide ACC's pharmaceutical policy, we will assess the different options against these principles to ensure that the final policy represents the most principled approach.

Next Steps

6.7

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If PGC agrees, Operational Policy will lead a policy project, in consultation with Clinical, Legal, Policy, Client Services Delivery, and the EBR team that looks objectively and holistically at how ACC should fund pharmaceuticals.

7.2 In **Table 1** below we outline an indicative timeline for the project:

Table 1. Indicative anemic for reacted pring Acc 5 pharmaceutour poincy		
Timeframe	Action	
December 2020 – February 2021	Data collection and analysis / research and planning	

Table 1: Indicative timeline for redeveloping ACC's pharmaceutical policy

March 2021	Options development and analysis		
April 2021	Internal consultation / engagement with EBR		
May 2021	Report back to PGC with the policy and recommendations		
May 2021	External consultation		
May-June 2021	Implementation into Promapp / internal comms		

- 7.3 Phase one will involve comprehensive data collection and analysis to identify:
 - Proportions of pharmaceutical requests accepted and declined;
 - Reasons for why requests are declined;
 - Proportion of requests referred to internal Pharmaceutical Clinical Advisors;
 - Proportion of requests automatically approved;
 - Proportion of requests that are for one-off prescriptions vs. renewals;
 - Proportion of requests made through MyACC;
 - Estimation of prescriptions that are not requested for reimbursement (i.e. liability); and
 - Customer outcomes where available.

7.6

7.4 It will also be used to more thoroughly understand the different elements of pharmaceutical funding. For example: problem areas, recent reviews, receipt requirements for reimbursements, how informative request forms are, etc.

7.5 Phase two will involve options development and analysis. We propose to consider a range of options and assess them against the guiding principles. This phase will also involve risk assessment.

Phase three will involve consultation on what we consider the most principled approach, to gain business insights into the policy. This will include engagement with the EBR team and the Clinical Governance Group. This phase will end with a report back to PGC on the recommended policy.

7.7 Phase four will be implementation of the policy and processes into Promapp. As part of the on-going management of the scheme, we will propose checks for monitoring ACC's ongoing pharmaceutical expenditure and client outcomes. Out of Scope

Senior Operational Policy Advisor



Appendix 1

Current documentation

Promapp pages:

- Pharmaceuticals policy
- Cannabis, ketamine and other illegal drugs policy
- Desensitisation policy
- First and Stable phase pharmaceuticals policy
- Therapeutic products policy
- Receipts required for client pharmaceutical reimbursement policy
- Non face-to-face repeat prescriptions prescriber fees policy
- Treatment policy
- Access cannabis-based medicine and product funding requests

CHIPs pages:

- Deciding entitlement process
- Processing reimbursements process
- Set-up direct billing process
- Arrange consumables process
- Determining entitlement for rabies process
- Requests to fund pemetrexed process
- Referring a task to the National Pharmaceutical Advisory team process
- Entitlement criteria test process reference
- Check pharmaceutical process reference
- How ACC pays for pharmaceuticals process reference
- Corporate Pharmaceutical Advisor consideration list
- ACC2530 Cox-2 inhibitors prescriber checklist
- ACC1173 Tramadol prescriber checklist
- Tramadol Funding Post 1 June 2010
- Dextroproxyphen Withdrawal & Funding Management Post 1 August 2010
- Fentanyl Internal CA Advice
- Venlafaxine Subsidies

FLIS:

• ACC1171 'Request for pharmaceutical funding'

Operational Policy Paper Cover Sheet

	1		
Date	9 April 2021		
Title	Pharmaceuticals policy proposal		
Outcome sought	Agreement to an updated framework for assess	sing pharmaceutical requests	
Action sought	Decision 🛛 Information 🗌 Consideration 🗌		
Strategic alignment			
Value proposition		Impact (+ve)	
	Number of tasks in pharmaceutical queue	н	
	Number of written guidance requests	L H	
	Length of time a task stays in queue		
	Decision timeframes	L	
	Number of FTE required to manage process	L	
	Number of reviews	L	
	Overall organisational capability impact	L	

Out of Scope

Manager Clinical Oversight & Engagement

х

Out of Scope

Х

Operational Policy Manager

Out of Scope

Out of Scope

Manager Operations Payments

Manager Claims Assessment

Operational Policy Paper – policy proposal

Pharmaceuticals policy proposal

1 Purpose

- 1.1 This paper seeks agreement to a refreshed framework for ACC to determine funding for pharmaceutical requests. The objective of the framework is to improve operational capability, by streamlining these requests, and improve ACC's consistency of pharmaceutical decision-making.
- 1.2 This work has been endorsed by the Policy Governance Committee (PGC).¹ Final approval of the proposal sits with Support & Capability Services and Clinical Services, however, a report back on the implementation of the final product will be shared as appropriate to PGC and others across ACC.

2 Recommendations

- 2.1 It is recommended that you:
 - a) <u>Note</u> that it is the appropriate time to consider pharmaceutical issues given ACC's reduction in pharmaceutical spend over the last five years, and operational changes and challenges related to ACC's current pharmaceutical policy.
 - b) Note that there are numerous issues to work through including:
 - i. ACC's risk threshold for approving requests without investigation (including where the request is a renewal);
 - ii, The criteria that are used when an investigation is required; and
 - iii. Proof of purchase requirements for reimbursement.
 - c) <u>Note</u> that there are a number of options that have been explored in terms of approving requests without investigation. This includes automatic approval based on public subsidisation, New Zealand regulation, an ACC specific approval list, and one-off requests.
 - d) <u>**Support</u>** the proposal that all *subsidised* pharmaceuticals are approved and paid without further investigation.</u>
 - e) <u>Support</u> the proposal that *renewals* for unsubsidised pharmaceuticals are approved and paid without reinvestigation for Serious Injury (SI) clients and clients with complex mental and/or physical injuries (unless specified in the original request that renewals should be reinvestigated).
 - f) <u>Support</u> the steps that should be taken to investigate requests for nonsubsidised pharmaceuticals and renewals that require reinvestigation.
 - g) <u>Support</u> the proposal that all requests \$50 or under do not require receipts as proof of purchase. This constitutes an extension of the current MyACC practice to all requests (including form-based requests).

¹ The proposal was presented at the December 2020 PGC meeting. The scoping paper for the project and the meeting minutes can be requested for further information.

3 Value proposition

3.1 The proposal outlined in this paper is expected to improve ACC's operational capability by reducing the number of pharmaceutical requests that require hands on management, while maintaining the same expenditure (ie expenditure does not increase in response to operational changes). In particular, the following metrics are expected to improve:

Operational capability	Current state	Expected impact	Impact size
Number of tasks in pharmaceutical queue	Average 258 tasks per week	Large reduction (aim >50%)	HIGH
Length of time a task stays in queue	More than 35 days (more than 30 days over targets of 5 days)	Reduced timeframes to meet targets (of 5 days or less)	HIGH
Decision making timeframes	Up to 3 months for reimbursements, more for pre- approval	Reduced timeframes for 85% of requests to automatic	HIGH
Number of FTE required to manage process	Approximately 7 FTE per day (across multiple teams)	Reduced FTE (by at least 2-4 FTE)	HIGH
Number of written guidance requests	Approximately 1,800 annually	Reduction (up to approximately 50%)	MEDIUM
Number of pharmaceutical related reviews	Annually 500 claims have reviews attached that have a pharmaceuticals label ²	Reduced pharmaceutical related reviews likely	LOW
Overall pharmaceutical expenditure	Just under \$1.5 million per year	Same expenditure (ie doesn't increase)	NONE
Overall value		HIGH	

4 Problem definition

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While ACC is liable to cover injury-related pharmaceutical costs, it lacks a clear and consistent framework for managing approval and reimbursement requests:

ACC's approval policy and process is over-managed and over-complicated. Business units have changed their processes outside of existing policy in order to circumvent some issues, leading to inconsistent client, provider, and staff experiences.

ii. ACC does not have a clear position on when it funds unsubsidised and/or unregulated pharmaceuticals. This is in part due to ACC's current policy formulation which is not communicated transparently.

5 Background

i.

5.1 New Zealand has a complex system for funding and assessing pharmaceuticals. This includes agencies like Pharmac (for public funding/subsidisation) and Medsafe (for regulating), as well as health practitioners for prescribing at an individual level. Pharmaceuticals subsidised by Pharmac subsidised are almost always Medsafe regulated as well, and have therefore undergone robust approval processes to

² Not all of these reviews will be for the pharmaceutical element of the claim though.

ensure safety and efficacy. Subsidisation of a pharmaceutical also signals that it is an accepted and common form of treatment in New Zealand.

- 5.2 ACC has a distinct role in this system. It is liable to cover the costs of pharmaceuticals that have been prescribed by a treatment provider with prescribing rights, to an ACC client, for a covered injury or condition. However, ACC's decision to fund an entitlement is independent of a treatment provider's decision to prescribe the pharmaceutical. This is because ACC is required to take additional factors into account (besides therapeutic effect), such as the nature of the specific injury and likely benefit of the treatment relative to cost.³ In terms of pharmaceutical funding, the Accident Compensation Act 2001 (the Act) does not preclude ACC from funding unsubsidised and/or unregulated pharmaceuticals where these factors are met. For example, new chemotherapy drugs that have not (yet) been assessed by Medsafe.
- 5.3 ACC receives funding requests via forms like the ACC1171 Request for pharmaceutical funding, which allows prescribing treatment providers to seek approval for ACC funding, and the ACC249 Prescription reimbursement form, which allows ACC clients to seek reimbursement for costs already paid.⁴ In 2018, ACC also introduced MyACC as an online platform for clients to request reimbursement.
- 5.4 In December 2020, the Policy Governance Committee (PGC) endorsed work to redevelop ACC's pharmaceutical policy in line with the following principles:
 - a. legal risk and compliance;
 - b. consistency of decision-making (for pharmaceuticals and other entitlements);
 - c. restoring maximal rehabilitation and health outcomes for clients;
 - d. reducing active claims management to the greatest extent possible; and
 - e. maintaining ACC's responsible stewardship of scheme costs and boundaries.

Recent data trends

5.5 Trends over the past five years indicate that what may have been appropriate steps for ACC to take previously are no longer necessary or practical due to wider health system shifts. For example, ACC's current total pharmaceutical expenditure has reduced to less than a third of what it was in 2016. The number of claims and payments has also reduced, but less dramatically. This is captured in the table below:⁵

Table 1: ACC	s expenditure on pharma	iceuticals 2010-2020

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Year	Accepted Claims	Number of Payments	Cost per claim	Total Payment Amount
2016	12020	79060	\$389	\$5,029,968.08
2017	11642	76876	\$339	\$3,165,847.28
2018	11513	71676	\$193	\$1,600,477.21
2019	10652	<mark>65296</mark>	\$101	\$1,365,758.30
2020	10312	58470	\$141	\$1,427,347.44
% reduction	15%	25%	64%	72%

³ Schedule 1 of the Accident Compensation Act 2001.

⁴ Pharmacy direct billing is also set up for some pharmacies which allows them to bill ACC directly. In these instances, ACC reimburses an approved pharmacy on behalf of the client.

⁵ The 2019 drop in expenditure appears to be due to high cost items being less expensive this year.

- 5.6 Pharmac subsidisation is a key contributor to ACC's reduced pharmaceutical spend. Many of the drugs that were cost drivers in 2016 have since become subsidised. In particular, in 2016 the drugs Pregabalin, Pemetrexed, Ledipasvir/Sofosbuvir, and Celecoxib were all high cost items for ACC. Since becoming subsidised, ACC pays less to fund more clients. For example, in 2016 Pemetrexed alone (a common chemotherapy drug) cost ACC almost the same amount as the total 2020 spend on pharmaceuticals, and was only used by 52 clients.⁶
- 5.7 Approximately 85% of the requests ACC approves are for subsidised drugs, and expenditure on these requests has remained consistent at about \$500,000 per year. This indicates that subsidised drugs are high volume and low cost.⁷ Requests for non-subsidised drugs, on the other hand, are usually high cost and low volume. For example, in 2020 non-subsidised drugs (approximately 15% of requests) accounted for more than two thirds of ACC total pharmaceutical expenditure.

Transition to Next-Generation Case Management

- 5.8 ACC's transition to Next-Generation Case Management (NGCM) has had a few implications for pharmaceutical funding. One implication is that the policies that were once appropriate for a smaller number of familiar users are not appropriate in a system where frontline staff with limited prior knowledge of the area are required to apply the policies. In particular, there are currently 12 Promapp and CHIPs pages to navigate when deciding how to manage a pharmaceutical request.
- 5.9 Another implication is that under NGCM, a new and poorly documented process for managing pharmaceutical requests was put in place which makes the process hard to understand. This is discussed further in the next section.

6 Issues

6.1

6.2

Primary issue: ACC's approval process is over-managed and complicated

ACC accepts a large majority of pharmaceutical requests where the recipient already has cover;⁸ however, it is a long approval process and requires significant internal resourcing. Currently, there can easily be ten touch points with ACC due to constant back and forth between the Payments team, Treatment and Support teams (T&S), Recovery Team Members (RTMs), and Clinical teams.

Under NGCM, all pharmaceutical requests are now channelled directly to the Payments team in the first instance. The way this happens is via the following mechanisms:

 MyACC (through a reimbursement submission) generates a task for Payments which is placed directly into its reimbursement queue. Where required a client emails <u>MyACCReceipts@acc.co.nz</u> which Payments accesses.

⁶ As a few other examples, Pregabalin for 400 clients in 2016 cost over \$800,000, while in 2020 it was \$5,500 for a greater number of clients. Celecoxib was approximately \$66,000 for 700 clients in 2016, and just \$45,000 for over 3,000 clients in 2020.

⁷ This is a proxy by looking at requests under \$18, but the actual figure of subsidised requests might be slightly lower.

⁸ It's hard to get this information as ACC does not keep good records where it declines entitlements – decline decision letter are about 3% of total requests, but this is not the majority of decline requests.

- Forms that are physically mailed into ACC's service centres are scanned and a task is created and sent to the Payments queue.
- A client who has a dedicated Recovery Team Member (RTM) (in Partnered Recovery or Supported Recovery) can email their RTM a picture of a receipt and request which is forwarded to the Payments team.
- 6.3 Starting with the Payments team, ACC currently has a three-tier approval process. Each tier of decision making uses different criteria, and to date many of these criteria are not captured in policies (either papers or Promapp). The main triage steps and criteria are:
 - 1) Payments assess the request and approves and pays if:
 - each item on the request is under \$18;
 - the total cost of the request is under \$50; and
 - the medicines listed are 'standard' by Payments own assessment.⁹
 - 2) Where requests do not meet these criteria, T&S approve them (and send them back to Payments for payment) if the request meets:
 - 'First phase' criteria which includes being under \$80 per item, prescribed within seven days of a treatment provider's consultation, for a covered injury, and dispensed within three-months; or
 - 'Stable phase' criteria which includes having been looked at by Pharmaceutical Clinical Advisors (PHA) in the last six months, having no changes to the script (eg dose strength or frequency), and expected rehabilitation or recovery goals are being achieved and documented.
 - 3) If these criteria are not met, requests are referred to PHA for advice (PHA's criteria are discussed in the next sections).

Where a client is being managed by an RTM, the RTM also has the delegation to approve or decline pharmaceuticals outside of this process, for example if they have a client call in urgently for approval.

Resourcing from each team involved is high (at least 7 FTE total but significantly more is required to keep up with queue numbers) and clients can wait months to receive payments that they are entitled to. In particular, the Payments team cannot prioritise reimbursements over other payments (eg weekly compensation payments) and so pharmaceutical reimbursements are often delayed.

An unintended consequence of shifting work between teams is that in some cases the task can't be accessed by another team, so they create a new task to refer on and close the original task. This generates a heartbeat survey to the client who naturally provides poor feedback about their experience with ACC because they haven't received their reimbursement yet.

6.4

6.5

6.6

⁹ "Standard drugs" is a category made and used by Payments to help triage and includes Paracetamol, Ibuprofen, Tramadol, Codeine, Aspirin, Diclofenac, Flucloxacillin, Amoxicillin, Augmentin, Nortriptyline, Gabapentin, Dihydrocodeine, and Prednisone. All of these drugs are subsidised, but this is not an exhaustive list of subsidised drugs.

Renewals

- 6.8 Step 2 in the triage means that requests are assessed under different criteria depending on whether or not they are a renewal (something ACC has approved in the past). Currently ACC's policy is that all renewals need to have been assessed in the last six months by PHA. In practice this doesn't occur if it meets the criteria in Step 1.
- 6.9 Where a task is referred to the pharmaceutical queue in T&S (Step 2), renewals currently make up the bulk of the queue despite renewals only making up approximately 20% of total ACC pharmaceutical requests.¹⁰ As an example, **Figure 1** outlines an average picture of the pharmaceutical queue. In this instance, there are 76 tasks waiting in the queue of which 32 are renewals, 10 are for cannabis related products, and 9 are for melatonin (a subsidised pharmaceutical). This indicates that renewals take up a disproportionate amount of queue space, as do similar types of requests for which there is likely a common decision. For example, ACC would usually always decline cannabis requests and approve melatonin requests. However, currently these requests are all assessed individually.

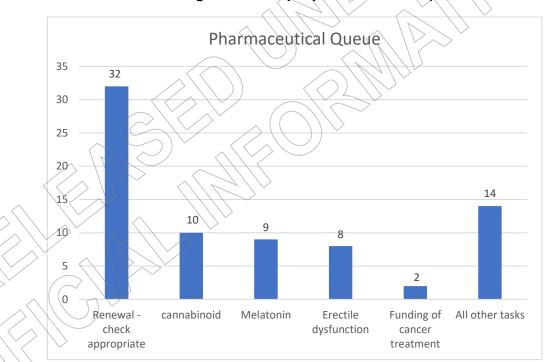


Figure 1. Example pharmaceutical queue

<u>Key questions:</u> what should ACC's position be on which requests are approved and paid without assessment and which will require assessment? Where is the appropriate checkpoint for renewals?

¹⁰ For example, a random check of a T&S queue indicated that 32 out of 75 tasks in the pharmaceutical queue were for serious injury renewals.

Secondary issues

Investigation criteria are not transparent

- 6.10 Where investigation of a pharmaceutical request is required before a decision to approve or decline can be made (currently Steps 2 and Step 3 in the triage above), ACC's criteria are not transparent. This is partly due to different criteria existing at different steps of investigation. While T&S currently use the 'first phase' and 'stable phase criteria', PHA use a different set of criteria. These criteria include:
 - Whether rehabilitation outcomes are being achieved;
 - Evidence about the efficacy and safety of the pharmaceutical;
 - Regulation;
 - The client's total pharmaceutical regime;
 - What other treatment options have been tried; and
 - How reasonable the cost is.
- 6.11 Even with these criteria, ACC does not always do a good job rationalising how the factors come together to make a decision, particularly where a request from a specialist is declined. For example, ACC might decline to fund a chemotherapy drug on the basis that it is not regulated in New Zealand for the client's circumstances. Given that an oncologist may have prescribed the chemotherapy, using similar criteria as PHA, it is not evident why ACC's opinion should be preferred.

<u>Key questions:</u> What evidence is required for ACC to make an informed decision? How does cost play into the decision? How shou d ACC factor external clinical opinions into its decision making.

Proof of purchase practices are inconsistent

6.12 Generally, ACC requires receipts for proof of purchase before it reimburses a client. However, under MyACC this is not required for requests under \$50. The different business practices between MyACC and form-based requests creates inconsistencies in client experiences, and potentially creates access barriers for the majority of clients not using MyACC.¹¹

The risk associated with forgoing an entitlement check by allowing ACC to reimburse clients without proof of purchase is not clear at this point

<u>Key questions:</u> what is ACC's position on proof of purchase for reimbursements? What is the appropriate limit for requiring receipts?

¹¹ While usage on MyACC is growing rapidly, it is still not the primary platform used to make pharmaceutical requests, meaning that most clients require receipts for every request.

7 Framework proposal

Primary issue: approval process and automation

- 7.1 In developing options regarding the threshold for approving requests without investigation, the options have been assessed against the agreed principles:
 - i. Legal risk and compliance how well the approach meets ACC's legislative requirements and manages legal risk.
 - ii. Consistency how consistent decision-making is under the approach including how similar it is to the way ACC makes other kinds of decisions.
 - iii. Outcomes for clients how consistent and good customer experience is.
 - iv. Operational Capability how well the approach reduces active claims management.
 - v. Cost how well the approach maintains ACC's responsible stewardship of scheme costs and boundaries.

Options analysis

- 7.2 **Appendix 1** outlines the options and the full analysis of them against the principles. While elements of status quo exist in the outlined options, status quo as an option has been discarded.
- 7.3 The options are:

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- i. **Option 1 Subsidisation:** ACC could approve all pharmaceuticals that are Pharmac subsidised without assessing them further. ACC's automatic approval would be low cost as it would only pay \$5 for standard prescriptions or \$15 for specialist prescriptions, and other high cost items would be investigated fully.
 - **Option 2 New Zealand regulation:** ACC could approve all pharmaceuticals that are Medsafe approved (for the client's condition) without investigation. ACC's automatic approval would only cover pharmaceuticals that have a clear foundation for them being a usual and safe course of treatment in New Zealand. Non-regulated pharmaceuticals would be investigated fully.
 - **Option 3 ACC approved list of pharmaceuticals:** ACC could approve all pharmaceuticals that were on a list of 'approved' pharmaceuticals based on standardness and uptake, as well as cost (similar to Payments list of 'standard' pharmaceuticals). ACC would need to compile this list, and a new set of criteria for determining which pharmaceuticals would go on this list.
- iv. **Option 4 One-off requests:** ACC could approve all pharmaceuticals that are being requested by a client for the first time without investigation, and then assess all renewals of that pharmaceutical in a full investigation.
- 7.4 **Appendix 1** provides a full analysis of the options including the benefits and disadvantages of each, and how each option ranks against the five principles. This is summarised below in **Figure 2**.
- 7.5 Under this analysis, Options 1 and 2 are the clear frontrunners. The key differences in the analysis are:

- Option 1 is more legally risk adverse because pharmaceuticals that are subsidised are always the "generally accepted means of treatment".¹² A pharmaceutical that is only regulated may not be the usual course of treatment. Preferring Pharmac subsidised pharmaceuticals means that a rigorous safety and efficacy assessment has occurred (via Pharmac's approval process) and that the pharmaceutical is the most accessible form of treatment.
- Option 1 is more financially responsible in terms of management of the scheme and scheme boundaries. For one, all high cost requests are required to be assessed, so cost is not a concern in this approach. Scheme boundaries are also largely maintained as only clients who already have cover will be able to access subsidised pharmaceuticals with automatic approval.
- Option 1 reduces operational burden to a greater extent. Subsidisation is easier to apply as a drug is either subsidised or it is not. Regulation is harder to apply as drugs are regulated for specific conditions, so it is necessary to check whether a regulated drug is approved for the right condition.

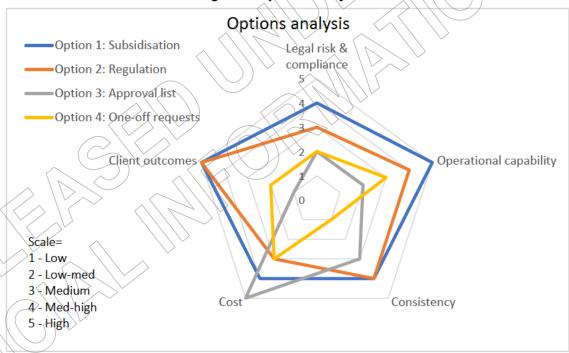


Figure 2. Options analysis

7.6

Consideration is also given to how renewals are treated under these options (also included in **Appendix 1**). Where ACC approves an initial request, it would be unlikely that it would not approve a renewal (especially under a robust decision-making framework). Therefore, most renewals should be approved without a reassessment. Under Option 1, a majority of requests would be approved without assessing the renewal. For consistency, ACC could extend approval to all non-subsidised renewals of pharmaceuticals that ACC has already approved previously. There are a few caveats:

¹² Schedule 1 of the Act requires ACC to consider what the generally accepted means of treatment in New Zealand is.

- Non-complex injury claims need to be assessed in terms of date of injury. This is to ensure that a client who received treatment for a covered injury doesn't exploit that cover for a later non-covered condition.
- All complex physical and mental injury clients (eg Serious Injury (SI) clients or clients with multiple physical and/or mental injuries) should have automatic renewal unless, in cases where the initial approval wasn't automatic, initial approval was given with specific criteria to be met for renewal.

Recommendation: Approve Option 1 - Subsidisation as the option for determining the threshold for approval without assessment.

Secondary issues

Investigation criteria are not transparent

- 7.7 Where a request requires further investigation, ACC's investigation criteria need to be transparent and accessible in one place. Note that this investigation would only applies to the pharmaceutical requests that do not meet the threshold for approval without investigation (approximately 15% of requests).
- 7.8 We propose that the steps in **Figure 3** (outlined below) are the appropriate steps for investigation. While many of these steps are already taken at various points in the current process, they are not laid out in one document.

Step 1 decline the request if	The pharmaceutical is not for a covered injury
	Another (at least 1) subsidised pharmaceutical with the same therapeutic effect has been tried and
Step 2 accept the	The pharmaceutical is regulated in New Zealand (ie Medsafe approved) for the covered condition
request if	and The pharmaceutical is prescribed by a treatment provider with the appropriate level of expertise for the condition or on the recommendation of an appropriate specialist (eg GP who indicates it's on the recommendation of a named relevant specialist).
)	Whether the pharmaceutical is regulated for the covered condition in another country
	The available research on safety and efficacy for the covered injury (in particular Phase 3* evidence is preferred but this alone is not a basis to decline)
Step 3 consider	The clinically assessed potential health benefit (likelihood and degree) in the prescribing treatment providers opinion
and assess based on	Sign off from specialist colleagues – counter sign clinical lead
based on	The overall appropriateness for the client's current situation
	Recovery outcomes to date
	The cost in relation to alternative treatment options
	Confirmation from external opinion that the treatment is appropriate
effective prior to	ials are usually the final trial of a new drug. While a drug will have already been found to be safe and Phase 3, Phase 3 specifically checks whether a new drug is more effective or safer than other available me therapeutic effect.

Figure 3. Proposed investigation steps and criteria

- 7.1 An example of this investigation in practice can be considered in relation to a client seeking cannabidiol (CBD) oil for pain management of a covered condition. CBD oil is a very common request, and is one that ACC declines to fund currently. Note that CBD oil is also not subsidised so requests would need to be assessed every time:
 - Step 1 is met as the CBD oil is for pain management of a covered condition, therefore the assessor moves to Step 2.
 - Step 2 is not met because CBD oil is not a Medsafe regulated pharmaceutical. Therefore, the assessor would move to Step 3.
 - Step 3 would need to be considered in light of the clients' specific circumstances; however, the request would likely fail due to the clinical research on CBD oils efficacy and lack of international regulation of the product. A second opinion is not required in this instance as the lack of evidence would be enough to decline the request. Therefore, the assessor could decline the request.
- 7.2 In the case of common requests, ACC will be able to create a 'blueprint' of the criteria in relation to the pharmaceutical (like CBD oil)¹³ to cut down time going through the steps. These blueprints would also be provided to Resolution Services to support their management of Review applications.

Recommendation: A single policy is implemented that includes the steps of investigation outlined in **Figure 3**.

Proof of purchase practices are inconsistent

- 7.3 The primary focus for determining ACC's receipt cost threshold is to implement a consistent practice across MyACC and paper-based requests. In doing so, consideration of whether the \$50 threshold could be higher or lower. Most pharmaceutical requests are under \$50 total. On average, ACC receives 258 pharmaceutical requests per week, for which approximately 57% are under \$50.
- 7.4 Since the MyACC practice of not requiring a receipt for requests \$50 and under was began in 2018, there have been no obvious issues with the practice. Moreover, ACC is considering forgoing the requirement for receipts for other types of reimbursements (eg funeral grants and travel costs), so this practice is not out of sync with where ACC is heading in terms of reimbursement policies.

The \$50 threshold is the same threshold that organisations can claim back GST for without a tax invoice. This means that ACC can still claim back GST on these payments without the receipts. Four options considered are:

- a) Extend the \$50 limit for requiring receipts to all requests (ie extend the MyACC practice to paper-based requests).
- **b)** Require receipts for all requests (ie extend the paper-based practice to MyACC).

¹³ The only CBD regulated product is Sativex, which is not regulated for pain management.

- c) Increase the \$50 limit for all requests so that a greater proportion of requests fall below the threshold (eg 80%).
- d) Decrease the \$50 limit for all requests so that a smaller proportion of requests fall below the threshold (eg 25%).
- 7.6 These options are outlined below assume that the policy would apply to both MyACC and paper-based requests:

Options	Advantages	Disadvantages
(a) \$50 three	hold The requirement for a receipt for low cost payments is a barrier for clients to claim back money ACC is liable to cover.	had to pay – eg fake requests for
	\$50 limit means that almost half of all requests (and in particular all high cost requests) will still require receipts to prove purchase.	paracetamol prescriptions.
	\$50 threshold aligns with the GST claim back threshold.	
	Since introducing this practice for MyACC clients, there is no data that indicates ACC's expenditure has increased.	
(b) Rec		This is a barrier to access for clients as
alwa		it means that clients need to have a
requ	red Without this as a proof of purchase, ACC is likely to pay for 'fake' costs.	rèceipt or be able to email it to ACC.
	likely to pay for lake costs.	Removing MyACC clients ability to receive reimbursement without
		receipts (particularly for regular
		claimants) may result in poor client
		experiences, particularly if ACC
		changes its mind on this again.
(c) High		Extending the receipt threshold to
three	hold payments is a barrier for clients to claim back money ACC is liable to cover. Raising the	k paper-based requests AND increasing the threshold amount will amplify the
	threshold reduces access even further.	risks associated with this practice.
		ACC may not be able to claim back
\sim \sim	\Rightarrow $X// \qquad $	GST.
(d) Low		Reducing the threshold for clients who
three		use MyACC and are used to the \$50
	an opportunity to assess the practice	threshold may reduce client
		experience. ACC shouldn't change the threshold too frequently without a clear
		reason to do so.
\mathcal{Y}		ACC may not be able to claim back GST.

7.7 We considerate it risky to extend the practice to paper-based requests *and* increase the limit at the same time. Therefore, we propose extending the practice but retaining the \$50 limit for requiring receipts to avoid too many changes at once. If ACC is not experiencing a change in volume, this limit could be reconsidered in 6- or 12-months' time.

Recommendation: Option (a) - extend the \$50 limit for requiring receipts to all requests and monitor the impact of the business practice.

8 Risks

8.1	There are a number of different risks associated with the recommended option:

What i	What is the risk?		Comment / mitigation
Financ	bial Making the approval process easier and the decline process harder may lead to ACC covering a greater number of pharmaceutical requests. Not requiring low cost receipts as proof of purchase has the potential for increased costs associated to illegitimate requests.	Small - med	The recommend approach means only approving <i>subsidised</i> drugs more easily, meaning that the financial risk is small. ACC's biggest costs by far come from unsubsidised pharmaceuticals, and these will still need to be fully assessed. Moreover, there will be operating cost savings by reducing the amount of resourcing required to manage pharmaceutical requests. Monitoring measures over the first year (and ongoing) will ensure that costs and volumes are not increasing in response to the policy change. Receipt threshold of \$50 is not recommended to be increased until the potential cost risks have been monitored. Annual monitoring and data analysis of ACC's costs will help further inform where costs are increasing and whether changes are required.
Legal	There is a risk that ACC covers requests it should not, due to the easier approval process, or does not cover requests that it should. There is a risk of fraud and waste and abuse from clients taking advantage of the easier approval process.	Small - med	It is unlikely that ACC would be challenged on an approval, even if it was in error due to the proposal of accepting subsidised requests. Where ACC declines a request, it should be made clear to the client that they can review the decision. Measures for volumes and costs will monitor for increased waste and abuse of the process – particularly looking at subsidised drug volumes which would increase due to abuse.
Client safety	A high trust approach means that ACC may not have the same oversight of a pharmaceutical regimes safety for a client	Small	ACC's ability to prevent harm is small as it usually only reimburses the costs of a pharmaceutical which is already being used and would be used regardless of ACC approval (especially where low cost). In some instances, ACC will require a second opinion, and this will introduce another safety check. Where a client needs to be informed about the risks of a treatment regime, ACC should trust that a prescribing treatment provider has informed the client rather than doing it itself (ACC is not a monitoring agency).
High c drugs	that can be problematic for a time (currently it is chemotherapy and medicinal cannabis). This approach does not address specific high cost drugs or provide an answer to those requests.	Small	The investigation criteria outlined out are designed to apply to all unsubsidised drugs equally well – for example the case of CBD oils is explained in terms of the investigation. ACC should monitor spend and decision making on current and emerging drugs to ensure that the criteria does the right job to guide consistent decision making.
Pharm chang		Small	While the technical criteria may be subsidised, the actual cost will be able to play a proxy for whether or not something is subsidised (for example \$5 and \$15 is the usual subsidised costs). Subsidisation is easy to look up where ACC is unsure.

9 Next steps

- 9.1 After seeking support from Support & Capability Services and Clinical Services, the implementation phase will begin. Implementation is considered in two streams of work:
 - Automation of the reimbursement process (for all subsidised pharmaceutical requests) will be completed in an Agile Release Train (ART), along with other reimbursement processes (such as travel reimbursements). This part of implementation is focussed on the system side of things including channelling all pharmaceutical requests to Eos (from the MFP system) and creating business rules around what the system can automatically approve and what needs to be created as a task for T&S to assess. This is intended to be completed as a Program Increment in August 2021.
 - 2) Lining up other business practices prior to automation. This stream of work will focus on lining up the business through policy changes on Promapp and business communications to ensure that elements of the policy are put in place prior to the roll over from MFP to the Eos system. This means that all of the current Promapp and Chips pages related to pharmaceuticals will be replaced by a single policy.
- 9.2 After implementation, key performance indicators will be monitored at 6- and 12month intervals; in particular:
 - Tasks in the pharmaceutical queue
 - Average time tasks sit in the pharmaceutical queue
 - Written guidance requests
 - FTE managing the process of approving pharmaceutical requests
 - Average length of time that clients wait for payment
 - Pharmaceutical related reviews
- 9.3 These performance indicators will be assessed against costs and volumes to ensure that the costs are not increasing significantly in response to the decrease in hands on management of requests.

10 Consultation

10.1 The following table reflects views from across ACC in regard to the proposal:

Stakeholder/ Team	Comment	Action
Out of Scope	I am not sure exactly what the problem is that led to this paper.	Refocussed on operational
Principle	Pharmaceutical Policy has been in place since 2003 and	improvement and consolidating
Clinical	operational processes to manage funding requests where	assessment criteria into one place.
Advisor	operationalised by 2005. Business rules were unilaterally changed in 2018, leading to an inconsistent client experience hence there is an opportunity to refresh the status quo, however	Included reference to recovery outcomes.
	this paper does not build on the work to date which has moved from a cost management focus to a client outcomes focus. The focus of this paper seems to be on internal process	Language has been improved where appropriate.
	improvement: to match NextGen case management and enabling more frontline decisions. However, using terms of 'subsidisation and regulation' are not easy concepts for frontline staff and does not keep alignment with a recovery outcome	Specific change to using "acute" and "ongoing" has been kept as "one-off" and "renewal" because this distinction is capturing a different
	focus. I have changed the strategic implication for the paper: it is	

	to improve process (not policy) and client experience, and suggested that this be built around ensuring cover, entitlement and outcomes in a language more understandable to staff: acute pharmaceutical use and ongoing pharmaceutical use. I note and corrected some terminology – 'first world' and 'problem drugs' which are not the usual descriptors for equitable or appropriate global identification or medicines labelling.	concept than the suggested change.
Out of Scope Clinical Services	Support for the recommendations, in particular Option 1 over Option 2, and the need for some evidence that medicine was prescribed either receipts or copy of prescription so agreement not to increase the \$50 limit. Feedback to tighten up the assessment criteria so that a second opinion is not required so frequently, but also note that provider expectations around when this would be required would also make the process easier.	Amended the assessment criteria as suggested and included an example of how it works with CBD as suggested.
Out of Scope Payments	Support for the recommendations. Reiteration that Payments should be the last port of call, not the first.	Removed "process" elements such as reference to who should do what and when, and moved to be a next step
Out of Scope Client Services	Support for the recommendations. Concern about potentially moving all triage to Treatment & Support and discussing further with team.	Removed "process" elements such as reference to who should do what and when, and moved to be a next step
Out of Scope CO Office	General support but note of inconsistency about whether a check for injury relation is included as part of Option 1.	Clarified that injury relation is not included in 'automatic' approval, but that renewals for short term clients need to be checked.
Out of Scope	Agree in princ ple with an automated approval process for pharmaceuticals that ar Pharmac funded and Medsafe approved, and then a more in-depth process for 'other' pharmaceuticals that require further investigation, noting that the starting point should be that depending – n the nature of the claim presented to us, the degree of investigation before accepting will vary. So, we also agree with the proposal that ACC can justify not doing an in-depth assessment before funding a drug if a drug is funded by Pharmac, and prescribed by a treatment provider, and there is an open claim we can accept that is sufficient. Note that the issue we're trying to avoid is the injury related check, but need a bit further discussion with Legal and Integrity. We think the prescribing criteria for requests that are not automatically accepted can also be presented in a more flexible format by combining sections 3 and 4 so that they are instead framed as 'considerations to take into account'. This would mean ACC's decision maker can place more or less weight on the considerations they consider relevant. It should also be explicitly noted that it is the treatment provider who should be outlining how many of the criteria in sections 3 and 4 are met, i.e. you could easily infer that ACC is doing an investigation, as opposed to an assessment of an application (we would think this too is particularly important for the nonapproved drugs where we would expect the provider to provide the detail, is this what is envisaged?).	need to be checked. Make clearer what the basis of subsidisation means in terms of justifying not doing an in-depth assessment. Include Integrity Services in the consultation, and discuss further with Legal the legal risk. Use "investigation instead of "assessment" to reflect role of treatment providers Combine sections 3 and 4 of flow chart. Clarification about referring to referring to legal risk AND legal compliance.
	Legal compliance as framed in the table arguably highlights legal risk for each option rather than legal compliance.	

Out of Scope Policy team	General support.	NA
Out of Scope Integrity Services	Agreement in principle noting the opportunity for inadvertent and deliberate waste and abuse from clients taking advantage of the approval of subsidised pharmaceuticals. The risk is diminished for Pharmac subsidised drugs as the cost associated is low and the risk of negative press is low (eg if ACC funded a controversial drug without realising). We should focus on the high-risk claims like unsubsidised drugs, but should think about how we could pick up waste and abuse to minimise it.	Added measures to look at volumes and costs, particularly for the first year.
	Support retaining \$50 receipt threshold so ACC can claim back GST.	
Out of Scope Supported Recovery	Agreement with the proposal noting it aligns with other changes to reimbursement. The proposal will not have a lot of impact for Supported (or Partnered Recovery) other than to make the process easier.	NA
Out of Scope Portfolio	Support the proposal – in particular Option 1. Think that the receipt threshold could be made higher than \$50 though. A separate issue not covered is creating a more effective way to support clients needing to pay their pharmacy co-payment costs (ie through pharmacy direct-billing).	Noted that the current reimbursement Epic under the ART is specifically not looking at creating a system in which clients do not pay any co-payment prior to reimbursement, and that the key part of this work is to reduce ACC operational burden.

Out of Scope Senior Operational Policy Advisor

Appendix 1: Automatic approval thresholds

Options	Benefits	Risks/disadvantages	Principles
Option 1 – Subsidisation (medium-trust) Requests are assessed based on Pharmac's subsidisation schedule. All subsidised drugs are paid without further investigation and all non- subsidised drugs are assessed further Renewals are assessed the same way, however where a non-subsidised drug has been approved in the past then ACC does not have to reassess it for SI and complex injury clients Option 2 – New Zealand regulation (higher- trust) Requests are assessed based on Medsafe approval assessments. All drugs approved to treat the covered injury are paid without further assessment and all non-regulated drugs are assessed further Where a drug is regulated but not subsidised, ACC automatically absorbs the cost of that drug Renewals are assessed the same way, however where a non-regulated drug has been approved in the past then ACC does not have to reassess it SI	Benefits Easily approves a large proportion of requests (approx. 87%) Acknowledges clearly that ACC doesn't need to worry about low cost items Criteria are clearly linked to policy foundation and easy to describe No obvious cost increases Acknowledges clearly the role that Medsafe has already played to determine the safety and efficacy of the drug Criteria are clearly linked to policy foundation and easy to describe Na obvious cost increases Acknowledges clearly the role that Medsafe has already played to determine the safety and efficacy of the drug Criteria are clearly linked to policy foundation and easy to describe Large proportion of requests that should be approved are approved Fast process for clients waiting on reimbursement	Risks/disadvantages Makes cost a key aspect of ACC's approval process as automation is clearly linked to cost Chance of fraud if clients exploit automatic payment Doesn't acknowledge the input of other agencies as part of the automation point (ie Medsafe approved pharmaceuticals are reassessed) Potential cost increases as subsidisation alone isn't a key triage criteria Chance of fraud if clients exploit automatic payment Doesn't allow ACC to request a subsidised drug is tried first Potential for a very small proportion of requests to be approved that may have required more oversight There is a need to check what the regulation is for (what condition), not just that it is regulated,	Principles Legal risk & compliance: med-high (may approve some claims that shouldn't be covered be) Operational capability: high (reduced touch points and resourcing) Consistency: med-high (internal consistency) Cost: low-med (potential additional costs) Client outcomes: high (better clarity and timeframes) Legal risk & compliance: med (may approve some claims that shouldn't be covered be) Operational capability: med-high (reduced touch points and resourcing, but additional effort to check condition regulation is for) Consistency: med-high (internal consistency) Cost: medium (probable additional costs) Client outcomes: high (better clarity and timeframes)
and complex injury clients Option 3 - approval list of pharmaceuticals (low trust) Requests are assessed based on ACC's assessment of 'approved', and otherwise assessed further This would involve ACC compiling a list of 'approved' pharmaceuticals based on standardness and uptake, as well as cost. Means that ACC 'approves' drugs independently of Medsafe assessments Papawala are appeared the same way	ACC can decide to fund or not fund anything it likes Where a pattern of requests develops, ACC can decide how to handle the uptake of the drug	Which requires additional High operational resourcing to decide which drugs to approve on a drug-by-drug basis No framework to consider new drugs Does not recognise that a lot of this process has already been undertaken. Makes ACC entirely responsible for its decision making and may give ACC too much sector influence on which drugs to prescribe	Legal risk & compliance: low-med (heavily based on ACC's opinions) Operational capability: low (resource intensive to create and maintain approval list) Consistency: low-med (ACC considers other agency input) Cost: low (ACC can control costs) Client outcomes: low (clarity and timeframes aren't improved)
Renewals are assessed the same way Option 4 - One-off requests (low trust) Requests are assessed if they are the first instance of a request without assessment. Where a request is a renewal it is assessed Essentially pushes the burden of proof down the line to those that are renewed	Approves approximately 80% of requests easily Deals with the renewal question inherently	Doesn't solve the renewal issue where the claim is long-term, so it would be assessed every-time Involves a check of all previous requests for every request, so potentially high intensive Unbalanced client experience for those renewing something that was easily approved the first time	Legal risk & compliance: med (may approve some claims that) Operational capability: med (unbalanced work) Consistency: low (unbalanced decision making) Cost: med (no control over one-offs) Client outcomes: low-med (unbalanced experience)