

TABLE 1: SUGGESTED MEDICINES ACCESS PROGRAM COST RECOVERY FEE SCHEDULE

Responsible/accountable entity?	Activity	Suggested fee	Comments
MAP Governance			
Drug and Therapeutics Committee	Governance review of MAP (includes review of efficacy, safety, cost effectiveness and risk assessment for the health service organisation)	\$0 up to \$800 per MAP review	If ethics is required this would incur an additional cost. See IHPA document for suggested ethics costs. https://www.iHPA.gov.au/publications/development-table-standard-costs-conducting-clinical-trials-australia
MAP Establishment/ Set-up			
Pharmacy Department	Administration: departmental set up, providing advice on DTC approval procedures, review of protocol, protocol set up, establishment of dispensing procedures, start up meetings or site visits.	\$0 up to \$1500 for pharmacy department per MAP	
Ongoing management			
Pharmacy Department	Administration: managing ongoing documentation, handling of returned stock submission or review of adverse events, monitoring visits, email correspondence	\$0 up to \$1350 for pharmacy department per annum (from yr. two of the MAP)	
	Staff training (medication and MAP specific)	\$0 up to \$100 per MAP	This maybe included in the establishment fee
	Provision of on-call and call-back fees for clinical pharmacist	\$0 up to \$400 - \$500 per call back	
	Medication ordering, receiving, and/or stock tracking	\$0 up to \$100 per stock shipment received	
	Medication preparation, labelling	\$0 up to \$100 per hour	This is required for programs such as Expanded Access Programs, where the medicine is not registered with the TGA, therefore may require re-labelling.
	Medication dispensing and accountability	\$0 up to \$30 - \$80 dispensing simple/patient/service \$0 up to \$80 - \$150 dispensing complex/patient/service (compounding)	Medication dispensing may be covered by a patient co-payment, which is suggested in the CATAG MAP GPs
	Medicine storage	\$0 up to \$300 - \$500 per annum per MAP room temperature \$0 up to \$500 - \$800 per annum per MAP Refrigerator/freezer storage \$0 up to \$300 - \$500 per annum per MAP narcotic storage	
	Medicine destruction	Waive fees or charge according to commercial rates Per occasion of service e.g. \$100 per occasion	Costs for destruction vary according to health service organisation policy, safe operating practices and the requirements of each MAP
	Miscellaneous fee e.g. relabelling, consumables, high complexity	\$0 up to \$85/hour/staff required	From time to time additional costs may be incurred. Additional costs may need to be charged for MAPs of high complexity

References:

1. Independent Hospital Pricing Authority (IHPA). Determination of standard costs associated with conducting clinical trials in Australia, Standard List of Clinical Trial Items, June 2015 https://www.iHPA.gov.au/sites/g/files/net636/f/publications/determination_of_standard_costs_associated_with_clinical_trials_in_australia.pdf accessed May 2016
2. Queensland Health. Fee Schedule and Site Information for Commercially Sponsored Research Prepared by the Office of Health and Medical Research, July 2010 https://www.health.qld.gov.au/_data/assets/pdf_file/0023/153419/QH_Research_Fee_Schedule-no-path-qld.pdf accessed December 2017
3. Australian Government, Department of Finance. Australian Government Cost Recovery Guidelines, Resource Management Guide No. 304. Australian Government July 2014 3rd Ed. <http://www.finance.gov.au/sites/default/files/australian-government-cost-recovery-guidelines.pdf> accessed Jan 2016
4. Society of Hospital Pharmacists Australia, SHPA Committee of Specialty Practice in Investigational Drugs. Clinical drug trials services and fees. August 2011
5. The NSW Association of Directors of Pharmacy University Teaching Hospitals. Policy: Schedule of fees for clinical drug trials, NSW Teaching Hospitals Pharmacy Departments 2016-2017