National Efficient Price Determination
Standard List of Clinical Trial Items

June 2013

IHPA

This determination is made by the Independent Hospital Pricing Authority under subsection 131(1) of the National Health Reform Act 2011 (Cth).

Dated 28 June 2013

Shane Solomon

Mr Shane Solomon
Chair

Dr Tony Sherbon
Chief Executive Officer

SEAL OF INDEPENDENT
HOSPITAL PRICING AUTHORITY

Table of contents

Chapter 1 Overview

On 28 November 2012, the Pricing Authority received a Direction under the *National Health Reform Act* subsection 131(3) from the Commonwealth Minister of Health to determine the national efficient price for a list of standard items associated with clinical trials (Direction No. 1 of 2012) The list of standard items was previously determined by the National Health and Medical Research Council (NHMRC).

In determining the national efficient price for the list of standard items, the Pricing Authority has complied with direction in so far as:

(i) In performing the activity described in the Direction, the Pricing Authority must have regard to the matters set out in subsection 131(3) of the Act.

(ii) In addition, the Pricing Authority may, so far as the Act permits, have regard to the following matters:

(a) The actual activity of each item;

(b) Principles of cost-recovery; and

(c) Submissions from relevant parties, including clinical trial sponsors and private hospitals.

In determining the national efficient price of these items IHPA has been assisted by an advisory committee including representatives from clinical trial sponsors, hospitals and all Australian governments. A public submission process was also conducted.

Chapter 2 Explanatory Notes

The prices in Chapter 3 of this Determination were developed, through a consultation process involving a wide range of stakeholders,

The methodology used to complete the project featured the development of a discussion paper as the basis of a call for public submissions and visits to ten public hospitals and three private hospitals, three organisations involved in clinical trials in the primary and community services sector.

An advisory committee consisting of representatives of trial sponsors, trial collaborative and most jurisdictions provided expert technical input to IHPA throughout this process. A detailed report outlining the process is available on IHPA's website.

IHPA was required to use the NHMRC list of items that was developed as a result of the CTAG process. IHPA notes the concerns of some stakeholders that the list is primarily focussed on pharmaceutical trials and it is considered that further work is required to ensure the applicability of the NHMRC list to medical device trials, and until such time as this work is carried out, the table of standard costs should not be used for device trials.

Chapter 3 – National efficient price for list of standard items associated with conducting clinical trials in Australia

Major category	Item	Reference number	Standard cost
Sub-List 1 – Clinical Tests and Procedure Items			
Screening Visit and Health Assessment	Clinical services provided specifically for the purposes of screening and health assessment	1.1.1	Calculated per service based on trial protocol using standard costs for items 1.2.1, 1.3.1, 1.3.2, 1.5.1, 1.6.1, 1.7.1, 2.6.2, 2.6.3, and 2.6.4
Laboratory Tests/Procedures	Laboratory tests and procedures itemised under the MBS	1.2.1	140% of the MBS fee per laboratory test and/or procedure
Medical Imaging	Imaging examinations and procedures itemised under the MBS	1.3.1	140% of the MBS fee per imaging examination and/or procedure
	PET-FDG/FLT scans not itemised under the MBS	1.3.2	140% of the nearest equivalent MBS fee for PET-FDG per scan
Radiation Therapy	Radiation therapy planning and treatment itemised under the MBS	1.4.1	140% of the MBS fee including ROHPG component per service
Other Clinical Tests or Procedures	Other clinical tests or procedures itemised under the MBS	1.5.1	140% of the MBS fee per service
Specialist Medical Consultations	Specialist medical consultations itemised under the MBS	1.6.1	140% of the MBS fee per specialist medical (including GP) service 100% of ADA fee per specialist dental service

Major category	Item	Reference number	Standard cost
Nursing / Allied Health Consultations	Nursing/Allied Health consultations not itemised under the MBS	1.7.1	100% of the published IHPA price for public hospital outpatient services

Major category	Item	Reference number	Standard cost
Sub-List 2 – Clinical Trial Support Services			
Departmental Protocol Review	Departmental Protocol Review	2.1.1	$171 per protocol review
Departmental Establishment /Set up Fees	Departmental Establishment/Set up Fees	2.2.1	$2,000 for clinical trial unit per clinical trial $990 for pharmacy department per clinical trial $425 for pathology department per clinical trial $550 for radiology department per clinical trial
Departmental Ongoing Administration Fees	Departmental Ongoing Administration Fees	2.3.1	$1,005 for clinical trial unit per annum (from year two of the clinical trial) $500 for pharmacy department per annum (from year two of the clinical trial) $398 for pathology department per annum (from year two of the clinical trial) $200 for radiology department per annum (from year two of the clinical trial)
Pharmacy / Investigational Drug-related	Staff training (drug specific)	2.4.1	$224 per clinical trial
	On call and call in/call back fees	2.4.2	$400 per call in/call back

Major category	Item	Reference number	Standard cost
	Drug stocking	2.4.3	$45 per stock shipment received
	Drug preparation, labelling and re-labelling	2.4.4	$37 per drug preparation $85 per 25 containers either labelled or relabelled
	Drug dispensing and accountability	2.4.5	Dispensing – simple $37.00 per participant per service Dispensing – complex $92.50 per participant per service Accountability - $12.75 per participant per service Counselling - $14.80 per participant per service
	Drug transfer	2.4.6	$49 per drug transfer (excluding transport/courier costs)
	Drug storage and temperature monitoring	2.4.7	$50 per annum per clinical trial
	Drug destruction	2.4.8	$77 per drug destruction service (excluding off-site destruction fees)

Major category	Item	Reference number	Standard cost
Biospecimen-related	Biospecimen collection and processing (central and local)	2.5.1	$30 per biospecimen collected for analysis by central laboratories (excludes transport costs (e.g. courier costs**,** any required quarantine permits, etc.) as these costs vary depending on the amount of biospecimens being transported, the delivery location (e.g. within Australia or overseas) as well as the temperature at which the biospecimens need to be transported at).
	Biospecimen analysis (central and local)	2.5.2	140% of the MBS fee for the nearest equivalent test listed on the MBS
	Biospecimen storage (central and local)	2.5.3	Not determined, deemed to be included in 2.5.2
	Biospecimen destruction (central and local)	2.5.4	Not determined, deemed to be included in 2.5.2
	Tissue repository set-up and management	2.5.5	Not determined as cost is typically not incurred at trial sites
Clinical Staff/Resource Allocation	Coordinating principal investigator surcharge	2.6.1	$215 per hour
	Investigator allocation	2.6.2	$215 per hour
	Research nurse allocation	2.6.3	$60 per hour
	Clinical research coordinator (non-research nurse) allocation	2.6.4	$75 per hour

Major category	Item	Reference number	Standard cost
	Clinic/theatre usage	2.6.5	Not determined, as there was no reasonable basis, and cost typically not charged by trial host sites, theatre use is usually for standard of care services

Major category	Item	Reference number	Standard cost
Sub-List 3 – Non clinical services			
Project Development	Preparation of research proposal	3.1.1	$80,858 per research proposal (for non-industry sponsored trials only)
	Site selection including site feasibility assessment process	3.1.2	$2,597 per site selection (including site feasibility assessment process)
	Preparation and submission of applications to HREC and institutions	3.1.3	HREC (non-lead) and SSA = $3,098 per application per clinical trial HREC (lead) and SSA $3,953 per application per clinical trial
	Radiation safety and/or biosafety reports	3.1.4	$99 per radiation safety and/or biosafety report
	HREC (ethical) review fee	3.1.5	$3,000 per HREC (ethics) application
	Institutional (site assessment) review fee	3.1.6	$750 per institutional (site assessment) application
	Lead HREC/Lead site fee	3.1.7	$400 per additional site per annum

Major category	Item	Reference number	Standard cost
	Investigator meetings	3.1.8	$1,020 per Clinical Trials Manager/Coordinator attending an international investigator meeting $3,440 per Principal Investigator attending an international investigator meeting OR $287 per Clinical Trials Manager/Coordinator attending a domestic investigator meeting $882 per Principal Investigator attending an domestic investigator meeting
	Staff training	3.1.9	$638 per Clinical Trials Manager / Coordinator required to undertake staff training per clinical trial. $430 per Principal Investigator required to undertake staff training per clinical trial.
	Trial-specific equipment hire/purchase	3.1.10	$75 per trial-specific equipment hire/purchase for a biomedical engineering check
	IT set-up, equipment and maintenance	3.1.11	$37.50 per trial-specific IT equipment item for set-up
	Trial centre set-up and development	3.1.12	Not determined, as cost typically not incurred by trial sites

Major category	Item	Reference number	Standard cost
Project Implementation	Start-up meeting	3.2.1	$1,815 per start-up meeting
	Pre-screening activity	3.2.2	$4,003 per clinical trial
	Recruitment activity	3.2.3	$349 per potential clinical trial participant screened and assessed
	Medical records set-up, access and storage	3.2.4	$10 per medical record accessed (for clinical trial visits only i.e. excluding standard of care visits)
	Interpreter services	3.2.5	$52 per hour
	Ongoing administration, monitoring and reporting	3.2.6	$470 per participant per annum
	Data analysis (+/- study report)	3.2.7	Not determined, as cost typically not incurred by trial sites
	Trial centre data management, data analysis and ongoing administration, monitoring and reporting	3.2.8	Not determined, as cost typically not incurred by trial sites
	Amendment preparation and submission	3.2.9	$343 per amendment (excluding fee charged by the RGO and/or HREC for review)
	Amendment review	3.2.10	$275 per amendment reviewed
	Study close-out activity including preparation for audit	3.2.11	$693 for study close out per clinical trial

Major category	Item	Reference number	Standard cost
	Archiving of trial records	3.2.12	$750 per clinical trial
Participant-related	Participant payment	3.3.1	Not determined, any payments made at discretion of the trial sponsor
	Participant/carer time and inconvenience reimbursement	3.3.2	Not determined, any payments made at discretion of the trial sponsor
	Participant/carer travel	3.3.3	Not determined, any payments made at discretion of the trial sponsor
	Participant/carer parking	3.3.4	Not determined, any payments made at discretion of the trial sponsor
	Participant/carer meals	3.3.5	Not determined, any payments made at discretion of the trial sponsor
	Participant/carer accommodation	3.3.6	Not determined, any payments made at discretion of the trial sponsor
	Participant inpatient/overnight stay	3.3.7	Not determined, as no evidence of participants being charged in practice was found.
	Participant outpatient/day stay	3.3.8	Not determined, as no evidence of participants being charged in practice was found.