
Application 1400

Final Protocol to
guide the assessment
of Clinical
Neuropsychology
Assessment (CNA)
Services

April 2016

1. Title of Application

Clinical Neuropsychology Assessment (CNA) Services

2. Purpose of application

An application was received from the College of Clinical Neuropsychologists (CCN) of the Australian Psychological Society (APS), requesting Medicare Benefits Schedule (MBS) listing of Clinical Neuropsychology Assessment (CNA) services.

Clinical Neuropsychology is an applied science that examines the impact of both normal and abnormal brain functioning on a broad range of cognitive, emotional, and behavioural functions (American Academy of Clinical Neuropsychology 2007). It is the intersection of neurology, psychology and psychiatry (Kulas & Naugle 2003). Clinical Neuropsychology Assessment (CNA) services synthesize data from the patient interview, family member/guardian interview, record review, behavioural observations, and objective tests of cognitive, emotional and motor function to diagnose or give a prognosis and functional status for patients with neurocognitive, psychiatric and other medical disorders (Braun et al. 2011).

It is claimed that incorporating CNA into the clinical care of individuals with cognitive dysfunction can provide valuable specialist assessment, diagnosis, prognosis and the basis for sound management of nearly all disorders and medical conditions affecting the brain, on an ongoing basis (Kulas & Naugle 2003). In patients with a diagnosed condition, information from CNAs can define the patient's functional and cognitive limitations and strengths, and improve the quality of care (Kulas & Naugle 2003). Despite the clear rationale of CNA services, there seems to be a lack of studies on clinical outcomes associated with CNA (Allott et al. 2011). As CNA is an investigative medical service, and is not beneficial by itself, it needs to have an impact on patient management to benefit patients' health. A scoping search identified a study on change in patient management after CNA (Allott et al. 2011). Following CNA in a mental health service for adolescents and young adults, 11% of patients had a change of diagnosis, 52% had a changed approach to treatment, and 33% had increased or more appropriate access to services, education or work. In a study in patients suspected of dementia, there was less change in patient management after CNA (Geroldi et al. 2008). The change in a differential diagnosis of degenerative dementia usually does not lead to a therapy change, as an effective medical therapy against degenerative dementias is not yet available.

In Australia, CNAs are currently provided and funded by the Department of Veteran's Affairs (DVA), and accident compensation insurance schemes like Workcover, Motor Accidents Board (NSW) and Transport Accident Commission (Victoria). Public patients needing a CNA would have it funded through the States/Territories, however, patients seeking the services in private practice currently have to pay for it themselves. This creates inequity in the provision and access to CNA services. The applicant claims that only a small proportion of the people who need CNA currently receive it, in any setting. Funding through the MBS would allow more people to access specialised CNA services via Medicare items.

Adelaide Health Technology Assessment (AHTA), in the School of Public Health, University of Adelaide, as part of its contract with the Department of Health, drafted this protocol to guide the assessment of the safety, effectiveness and cost-effectiveness of CNA services in order to inform MSAC's recommendations regarding public funding of the intervention. This protocol was finalised after input from public consultation, and has been ratified by the Protocol Advisory Sub-Committee of the Medical Services Advisory Committee (MSAC).

3. Population and medical condition eligible for the proposed medical services

CNA covers a range of cognitive domains, including: intelligence, learning, memory, receptive and expressive language, visuospatial reasoning and psychopathology (Kulas & Naugle 2003). A referral for CNA should be considered when there is a question about a patient's cognitive functioning, or about a patient's competency (Kulas & Naugle 2003). Common indications for CNA include: changes in memory, poor attention and concentration, changes in language functioning, changes in visuospatial abilities, impaired executive function, changes in emotional functioning, and fluctuations in mental status. As this could occur in nearly all medical conditions affecting the brain, there is no specific disease or medical condition that defines the patient population.

CNA may be requested:

1. To provide diagnostic information for detection of dementia or other traumatic conditions.
2. When there are mild or questionable deficiencies on mental status testing, so a more thorough evaluation is needed to investigate the presence of abnormalities compared to normal aging.
3. When the patient's deficits need to be quantified, especially when predicting or monitoring the course of a disorder (recovery or decline).
4. To characterise the strengths and weaknesses of a patient as part of a management or rehabilitation plan.
5. When the neuropsychologist can provide specific necessary rehabilitation or therapeutic services.
6. For monitoring of treatment response.
7. When there is litigation that concerns the patient's cognitive status or functional potential.

Sources: ('Assessment: neuropsychological testing of adults. Considerations for neurologists. Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology' 1996; Harvey 2012)

It is claimed by the applicant that most people referred for CNA (who have one or more of the indications) will be patients suffering from/suspected of:

- Group 1: neurodegenerative diseases; a range of conditions which primarily affect the neurons in the human brain. This includes Alzheimer's disease, dementia, multiple sclerosis, etc.
- Group 2: acquired brain injury (ABI); brain damage caused by events after birth (non-congenital). This consists of two subgroups.

- Group 2a: non-traumatic brain injury (NTBI), which does not involve external mechanical force. This includes stroke, encephalitis, meningitis, etc.
- Group 2b: traumatic brain injury (TBI), which includes damage to the brain due to external mechanical force, e.g. from motor vehicle accidents, assault, sporting injuries, falls, birth trauma, etc.
- Group 3: Paediatric and Developmental disorders; psychiatric conditions originating in childhood, involving serious impairment in different areas, e.g. language disorders, learning disorders, motor disorders and autism spectrum disorders.

Prevalence and expected utilisation

An estimate of the number of people included in some of the groups who are most likely to be eligible for CNA services are shown in Table 1. It was estimated that in 2003, 483,300 people in Australia had a form of ABI (group 2) with disability. It was reported that 432,700 people had ABI and some activity limitations or participation restrictions, which is 2.2 per cent of the Australian population. Almost three quarters of these people (311,800) were aged less than 65 years. Among older people, neurodegenerative diseases/disorders such as Parkinson's disease or dementia can often be a cause of ABI. Few people (around 1,400/120,900) over 65 years listed ABI as their main disabling condition, as it is often one of several health conditions related to their disability (Australian Institute of Health and Welfare 2007). The Australian Institute of Health and Welfare also states that over 40 per cent of people with an ABI have a co-morbid mental health issue.

In 2004-2005, there were around 21,800 hospital stays for which the diagnosis was associated with TBI (group 2b), which means there were 107 hospital stays per 100,000 people. This group consisted of 69 per cent males, and there was a strong peak in TBI-related hospitalisations for males between the ages of 15 and 24 years (almost 300 hospital stays per 100,000 people). There was also a steep rise in hospitalisations for people older than 75 years, in males and females (Australian Institute of Health and Welfare 2007). Even though we can give an estimate on how many people fall within the patient populations, we do not know how many of them would actually benefit from CNA.

Estimates of paediatric and developmental disorders are difficult. Indeed the available official estimates (ABS 2012; AIHW 2004) group these disorders broadly across three main categories: intellectual/learning disorders, psychiatric disorders and sensory/speech disorders. Some Australian research has been conducted which provides an indication on the prevalence of autism spectrum disorders (Barbaro & Dissanayake 2010; Williams et al. 2008).

The ABS reported in 2012 that approximately 9 per cent of boys and 5 per cent of girls aged 0 to 14 years had a disability of some sort during 2009 (ABS 2012). Based on the 2009 Australian population age 0 to 14, this equates to over 500,000 children living with a disability in that year. The greatest proportion of children with a disability in the 0 to 4 age group were affected by sensory and speech disorders (63%), while 29 per cent had an intellectual disability. In this age group, nearly 40 per cent had a mental or behavioural disorder that lasted or was expected to last six months or more. By contrast 37 per cent of 5 to 14 year olds had a sensory or speech disorder and 61 per cent in that age group had an intellectual disability. Among 5 to 14 year olds, nearly 70 per cent had a mental or behavioural disorder lasting or expected to last at least six months (ABS 2012). Additional information published by the AIHW (AIHW 2004) is available in Supplementary Table 1.

Williams and colleagues (Williams et al. 2008) reported an estimated prevalence of autism spectrum disorders of 0.6 per cent in Australian children. Barbaro et al reported on a prospective surveillance study suggesting that 0.8 per cent of Victorian children at the age of two fulfilled diagnostic criteria for autism spectrum disorders (Barbaro & Dissanayake 2010).

Other groups potentially eligible for CNA (not listed in the table) include patients with seizure disorders; intellectual disability with neurological or psychiatric comorbidities; deficiency states; psychiatric or somatoform disorders with cognitive impairment; and, cognitive impairment secondary to other conditions such as cancer, connective tissue disorders and chronic diseases.

Table 1 Prevalence of most common disorders included in some of the groups eligible for CNA services

Groups	Subgroups/diseases/disorders (most common)	Number of patients in Australia
1. Neuro-degenerative diseases	a. Alzheimer's disease and other forms of dementia	298,000 patients (2011)(Australian Institute of Health and Welfare 2012)
	b. Parkinson's disease	80,000 patients (Parkinson's Australia)
	c. Multiple Sclerosis (MS)	23,700 patients (2009) (Australian Bureau of Statistics 2009)
	d. Amyotrophic Lateral Sclerosis/ Motor Neurone Disease (ALS/MND)	1,900 patients (Motor Neurone Disease Australia 2014)
	e. Huntington's disease	1,600 patients (Huntington's New South Wales 2001)
	f. Creutzfeldt-Jacob disease (and other prion diseases)	1,426 diagnosed cases from 1993-March 2010 (Klug et al. 2011)
2a. Non-traumatic brain injury (NTBI)	a. Stroke	375,800 patients (2009) (Australian Institute of Health and Welfare 2013)
	b. Brain aneurysm	NA
	c. Brain tumours	6,206 patients suffering from brain cancer (2009) (Australian Institute of Health and Welfare 2015b)
	d. hypoxia or anoxia (causes are e.g. stroke, drowning, heart attack, strangulation, asthma, drug overdose, carbon monoxide inhalation, poisoning)	NA
	e. toxic or metabolic injury	NA
	f. infection (e.g. encephalitis or meningitis)	Average annual hospitalisation rate encephalitis from 1990-2007: 5.2/100.000 (Huppatz et al. 2009)
	g. alcohol and drug abuse	In 2013-2014, around 122,000 people received care from alcohol and other drug treatment agencies. Forty per cent is for alcohol. (Australian Institute of Health and Welfare 2015a)
2b. Traumatic brain injury (TBI)	a. road traffic accidents b. assaults c. penetrating or open head injuries d. falls e. sports injuries (e.g. concussions)	In 2004-2005 there were around 21,800 hospital stays per year due to TBI (Australian Institute of Health and Welfare 2007)
3. Paediatric and developmental disorders	a. language disorders b. learning disorders c. motor disorders d. autism spectrum disorders	In a 2012 release of Australian Social Trends, the ABS reported that in 2009, 8.8% of boys and 5% of girls aged 0-14 years had some form of disability (ABS 2012). Based on a 2009 total Australian population of 21.7 million, of whom 19.1% were aged 0-14 in 2009 (or 4.1 million children), this equates to approximately 571 968

		<p>children living with a disability in 2009.^a</p> <p>Among those children with a disability in 2009:</p> <ul style="list-style-type: none"> • 62.8% aged 0-4 years and 37.1% aged 5-14 years had sensory and speech disorders; • 29% aged 0-4 years and 61.4% aged 5-14 years had intellectual disabilities; • 39.9% aged 0-4 years and 68% aged 5-14 years had mental or behavioural disorders that had lasted or were expected to last 6 months or more. <p>More detailed prevalence data stratified by disability types is available, but has not been updated since 1998. (See Supplementary Table 1).</p> <p>Williams et al estimated a prevalence estimate of 1:160 or 0.6% of Australia children met criteria for autism spectrum disorders a range of data sources (Williams et al. 2008). More recent reports based on a prospective surveillance study suggest, 1:119 (0.8%) Victorian children aged 2 years met criteria for autism spectrum disorders (Barbaro & Dissanayake 2010).</p>
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ABS = Australian Bureau of Statistics; NA = not available

^a 4.1 million x (8.8 + 5%)

It is recognised that the potential population for this intervention is quite large, and for the literature review might not be possible, in practical terms, to limit the population to any degree.

The precise demand or need for CNA services, and the current level of unmet need, are not known. It is estimated, based on the indications for CNA above, that not all patients suffering from neurodegenerative diseases, developmental disorders or ABI would need to be referred, and some patients not specifically mentioned in one of the groups might benefit from CNA services. However, according to the Royal College of Physicians and British Society of Rehabilitation Medicine, adequate neuropsychological input in patients with cognitive and/or behavioural problems should be available in any rehabilitation setting (Royal College of Physicians and British Society of Rehabilitation Medicine 2003). The number of CNA services will depend on the number of referrals from medical specialists (e.g. geriatricians, neurologists, neurosurgeons, rehab physicians, paediatricians, or psychiatrists). The applicant estimated there would be 27,120 assessments per year, based on one specialist referral per week per neuropsychologist, and the same number returning for feedback (i.e. every patient has two sessions, one for tests, one for results). It should be noted that this figure is based on the number of current neuropsychologists (supply driven), not on the potential patient pool. The applicant also claims that one third of assessed patients may require an annual review, so this would be around 9,040 services per year.

As it is not known if the demand for CNA services matches the supply, there still may be an issue with equity of access and a risk of distortion of access to neuropsychologists after the listing of CNA services on the MBS. Currently, usage of MBS items under the 'Better Access' initiative is greater in more advantaged socio-economic areas and less rural areas, especially with consultant psychiatrist items. Socioeconomically disadvantaged areas are also associated with lower activity rates for clinical psychologist services (Meadows et al. 2015).

4. Intervention – proposed medical service

A comprehensive CNA includes the identification and description of the cognitive and behavioural correlates of brain disease or neurodevelopmental disorder, information regarding prognosis and the formulation of treatment plans (American Academy of Clinical Neuropsychology 2007). During a CNA, scientifically validated performance-based tests of cognitive, motor, sensory and emotional functioning will be conducted (Braun et al. 2011). The six neurocognitive domains thoroughly assessed with CNA are: learning and memory, language, perceptual-motor skills (e.g. finding oneself lost), executive function (e.g. multi-tasking), complex attention (e.g. how long it takes to do things), and social cognitive skills (e.g. personality changes and behaviours). The selection of tests depends on the patient's medical history, interviews with the clinical neuropsychologist, observations made by the clinical neuropsychologist, symptoms and patient characteristics. Other relevant information, such as neuroimaging and laboratory results, may also be included.

The applicant claims CNA may be able to specify which areas of the brain are affected, and which syndrome/disorder is associated with it. Therefore it sits among the other neuro-clinical assessments for diagnosis, e.g. electroencephalogram (EEG), computed tomography (CT), magnetic resonance imaging (MRI) and single-photon emission computed tomography (SPECT). CNA is not likely to be replaced by technology, as there is a lack of clear prediction of cognition and functioning from cortical changes (visible through imaging), in late life (Harvey 2012). Neuropsychological testing does not provide good information for differential diagnoses for neuropsychiatric disorders, but it does provide information that cannot be obtained through other tests on abilities, motivation, and potential for future outcomes (Harvey 2012). It adds information to other (psychological, neurological, and neuroimaging) assessments.

CNAs may sometimes be repeated to measure change due to spontaneous recovery, treatment effects or deterioration in brain function. However, the first CNA can have a significant impact on the results of the subsequent one. These 'practice effects' can inflate results and invalidate the opinions or recommendations made for rehabilitation (*Neuropsychological Assessment of Children and Adults with Traumatic Brain Injury: Guidelines for the NSW Compulsory Third Party Scheme and Lifetime Care and Support Scheme* 2013). Therefore, timing of a CNA needs to be carefully considered and the number of tests should be kept to a minimum. At least 12-24 months between CNAs is recommended. However, the applicant claims it is possible to determine reliable change indices with regard to re-administered clinical assessments, allowing clinicians to determine reliably whether any change in score from repeated assessment is due to reliable improvement or deterioration whilst correcting for the fact that the client is undergoing a repeated administration of the instrument used.

The applicant proposes three CNA services for listing on the MBS:

1. Assessment. This is the assessment itself, where the tests are conducted. The duration of the assessment can take anywhere between one and eight hours. A short assessment is seen as 1-4 hours, a medium assessment is 4-6 hours and a long assessment is 6-8 hours. First assessments are generally medium or extended.
2. Feedback. Neuropsychological feedback requires the preparation of a written plain-language summary for the patient (or parent, carer or guardian), individualised recommendations and

verbal delivery of the feedback. There are basic or short feedback (1-2 hours) reports, and extended feedback reports (3-4 hours). The latter also includes a management plan.

3. Review. This would be a re-assessment (maximum one per patient per year) of either short or medium length, based on clinical need, to assess progress or decline over time.

CNAs are currently conducted in (1) tertiary medical centres, (2) primary care, (3) patient's homes, and (4) residential aged care facilities. The majority of need for CNA services is for patients under the care of specialists in private practices (or GPs in rural areas). CNA services would assist with diagnosis, management decisions and determining prognosis in many cases. In tertiary medical centres CNAs are funded and provided in some inpatient and outpatient units (both public and private hospitals). The use of these services is mainly diagnostic, but may also provide information for treatment and rehabilitation planning. For people who are immobile or anxious and scared to be away from home (e.g. with dementia), CNAs can be conducted in the patient's home or in a residential aged care facility.

The applicant claims CNAs should be performed by an Australian Health Practitioner Regulation Agency (AHPRA) endorsed clinical neuropsychologist, as these practitioners are the only service providers appropriately trained and credentialed to undertake CNA. Referrals should be made by specialists (e.g. geriatrician, neurologist, neurosurgeon, rehabilitation physician, paediatrician, or psychiatrist), and in order to support rural GPs and patients, the applicant proposes that rural GPs should be able to refer patients for CNA services after a consultation (e.g. tele-health) with a specialist physician. The applicant has suggested that other GPs should not be able to refer directly for CNA so that referrals are appropriately made and over servicing is limited.

5. Co-dependent information

Not applicable.

6. Comparator – clinical claim for the proposed medical service

Comparators are usually selected by determining the technology most likely to be replaced by the technology submitted for a new MBS item number. As stated earlier, some patients may currently be receiving CNAs, funded through the public hospital system, the DVA or accident compensation insurance schemes. Patients receiving the treatment through an alternative funding source are not considered comparators for the proposed assessment.

Currently, in the absence of funded CNA services, there are several paths a patient can take:

1. The patients pay for CNA themselves.
2. Cognitive and behavioural symptom assessment done through other specialties (e.g. general practitioner, psychologist, geriatrician, neurologist, neurosurgeon, rehabilitation physician, paediatrician, or psychiatrist). Most of these services would consist of brief mental-status type assessments e.g. the Mini-Mental Status Examination (MMSE) or the Montreal Cognitive Assessment. For patients suspected of dementia there is the Quick Dementia Rating System (QDRS) (Galvin 2015). These services are limited in scope, depth and breadth compared to a CNA. Assessment services currently listed on the MBS are shown in Table 2.

3. No CNA is done; only medical imaging and symptom guided treatment.

As stated on page 5, the precise demand or need for CNA services is not known. Therefore, it is also difficult to assess the number of patients who would benefit from CNA but currently miss out on the service, the number of patients who currently receive CNA but not in a timely manner (anecdotal evidence from the applicant suggests a waiting time of 18 months to three years or longer in the public system), and the number who currently access CNA services in a different setting who may switch to the MBS funded setting. The number of eligible patients could be anywhere between zero and a million Australians.

Depending on the comparator(s) chosen, the approach for the assessment would differ (i.e. it determines whether a health technology assessment is an appropriate framework or not for considering its impact). The potential approaches are:

- a) If the comparator is CNA funded by patients, it is not expected that there would be health outcomes which would differ, and only the financial impact of the change need be assessed, including potential uptake of the item from patients not receiving CNA in a timely manner in the public system.
- b) With comparator 2, other specialists providing behavioural and cognitive symptom assessment, a health technology assessment should be performed to see if any literature is available comparing the health impacts of the delivery of limited services by other specialties to CNA delivered by neuropsychologists.
- c) With comparator 3, no CNA (and symptom guided management), the safety, effectiveness and cost-effectiveness of CNA may be assessed.

For children, the applicants suggested that a CNA is currently the only option as there is no MMSE available for this group, and imaging is inappropriate. CNA is the approach of choice with this population and is accessed through the public system or out of pocket. For adults, comparator 1, 2 and 3 are relevant.

Error! Reference source not found. outlines some possible MBS items which could potentially be used by other practitioners, to perform limited cognitive and behavioural assessments (not full CNA), as described in b) above.

An additional item was considered: 80000, the psychological assessment and treatment item available through the Better Access to mental health care initiative. This item is for patients only with a diagnosed mental disorder, and so may be applicable to some of the groups in the eligible population; however, it is only available by referral from a General Practitioner, and so is not relevant to this application. Furthermore, the applicants indicated that those conducting item number 80000 would not be qualified to conduct CNAs.

Table 2 Current MBS items for patient assessment services

MBS item number	Specialty	Group	Service	Fee
132	Consultant physician (other than in psychiatry)	A4 – Consultant Physician Attendances to which no other item applies	Professional attendance of at least 45 minutes duration for an initial assessment of a patient with at least two morbidities (this can include complex congenital, developmental and behavioural disorders), where the patient is referred by a referring practitioner.	Fee: \$263.90 Benefit: 75% = \$197.95 85% = \$224.35
133	Consultant physician (other than in psychiatry)	A4 – Consultant Physician Attendances to which no other item applies	Professional attendance of at least 20 minutes duration subsequent to the first attendance in a single course of treatment for a review of a patient with at least two morbidities (this can include complex congenital, developmental and behavioural disorders)	Fee: \$132.10 Benefit: 75% = \$99.10 85% = \$112.30
141	Consultant physician or Specialist in Geriatric Medicine	A28 – Geriatric medicine	Review of Referred Patient, Initial Comprehensive Assessment and Management - Surgery or Hospital. > 60 minutes.	Fee: \$452.65 Benefit: 75% = \$339.50 85% = \$384.80
143	Consultant physician or Specialist in Geriatric Medicine	A28 – Geriatric medicine	Review of Referred Patient, Initial Comprehensive Assessment and Management - Surgery or Hospital. > 30 minutes.	Fee: \$282.95 Benefit: 75% = \$212.25 85% = \$240.55
145	Consultant physician or Specialist in Geriatric Medicine	A28 – Geriatric medicine	Referred Patient, Initial Comprehensive Assessment and Management - Home Visit. > 60 minutes.	Fee: \$548.85 Benefit: 85% = \$470.45
147	Consultant physician or Specialist in Geriatric Medicine	A28 – Geriatric medicine	Review of Referred Patient, Initial Comprehensive Assessment and Management -Home Visit. > 30 minutes.	Fee: \$343.10 Benefit: 85% = \$291.65
291	Consultant physician in the practice of his or her speciality of psychiatry	A8 – Consultant psychiatrist attendances to which no other item applies	Professional attendance where the patient is referred for the provision of an assessment and management plan by a GP or participating nurse practitioner, where the attendance is initiated by the referring practitioner and where the consultant psychiatrist provides the referring practitioner with an assessment and management plan to be undertaken by that practitioner for the patient, where clinically appropriate. > 45 minutes.	Fee: \$452.65 Benefit: 85% = \$384.80
293	Consultant physician in the practice of his or her speciality of psychiatry	A8 – Consultant psychiatrist attendances to which no other item applies	Professional attendance to review a management plan previously prepared by that consultant psychiatrist for a patient and claimed under item 291, where the review is initiated by the referring medical practitioner practising in general practice or participating nurse practitioner. 30-45 minutes.	Fee: \$282.95 Benefit: 85% = \$240.55
359	Consultant physician in the practice of his or her speciality of	A8 – Consultant psychiatrist attendances to which no other	A telepsychiatry consultation where: the patient is located in a regional, rural or remote area (RRMA 3-7); in the preceding 12 months, payment has been made under	Fee: \$325.35 Benefit: 75% = \$244.05 85% = \$276.55

	psychiatry	item applies	item 291; an outcome tool is used where clinically appropriate; a mental state examination is conducted; a psychiatric diagnosis is made; a management plan provided under Item 291 is reviewed and revised; the reviewed management plan is explained and provided, unless clinically inappropriate, to the patient and/or the carer (with the patient's agreement); the reviewed management plan is communicated in writing to the referring practitioner. 30-45 minutes.	
707	Medical practitioner (including a general practitioner, but not including a specialist or consultant physician)	A14- Health Assessments	Attendance by a medical practitioner to perform a prolonged health assessment, including: comprehensive information collection, including taking a patient history; an extensive examination of the patient's medical condition, and physical, <u>psychological</u> and social function; initiating interventions and referrals as indicated; and providing a comprehensive preventive health care management plan for the patient. >60 minutes.	Fee: \$268.80 Benefit: 100% = \$268.80

7. Expected health outcomes relating to the medical service

The health outcomes, upon which the comparative clinical performance of CNA services will be measured, are:

Primary:

- Mortality
- Quality of Life
- Psychological health

Secondary:

- Avoidance of inappropriate investigations and treatment
- Treatment delay
- Length of hospital stays
- Diagnostic yield

Safety:

- Psychological harms from testing / no testing.

For patients who currently pay for CNAs themselves (and who would make use of MBS-listed CNAs if funded), current management would be unchanged and no effects on health outcomes would be expected. An economic evaluation would therefore not be required.

If there is evidence of superior effectiveness or safety compared to investigations performed by other specialties, then a cost-effectiveness analysis or cost-benefit analysis should be performed.

If the comparator is 'no testing', non-inferior safety and superior effectiveness would be expected and therefore a cost-effectiveness analysis or cost-benefit analysis would be done (Table 3).

Table 3: Classification of an intervention for determination of economic evaluation to be presented

		Comparative effectiveness versus comparator			
		Superior		Non-inferior	Inferior
Comparative safety versus comparator	Superior	CEA/CUA		CEA/CUA	Net clinical benefit CEA/CUA
					Neutral benefit CEA/CUA
					Net harms None [^]
	Non-inferior	CEA/CUA		CEA/CUA*	None [^]
	Inferior	Net clinical benefit	CEA/CUA		None [^]
		Neutral benefit	CEA/CUA*		
Net harms		None [^]			

Abbreviations: CEA = cost-effectiveness analysis; CUA = cost-utility analysis

* May be reduced to cost-minimisation analysis. Cost-minimisation analysis should only be presented when the proposed service has been indisputably demonstrated to be no worse than its main comparator(s) in terms of both effectiveness and safety, so the difference between the service and the appropriate comparator can be reduced to a comparison of costs. In most cases, there will be some uncertainty around such a conclusion (i.e., the conclusion is often not indisputable). Therefore, when an assessment concludes that an intervention was no worse than a comparator, an assessment of the uncertainty around this conclusion should be provided by presentation of cost-effectiveness and/or cost-utility analyses.

[^] No economic evaluation needs to be presented; MSAC is unlikely to recommend government subsidy of this intervention

8. Fee for the proposed medical service

The following fees have been proposed by the applicant (Table 4). All estimated costs are based on the Department of Veterans Affairs (DVA) average hourly rate of \$148.91 and the indicated maximum hourly limit applies for each item; it is recognised that DVA rates are usually higher than MBS rates to ensure no out-of-pocket expenses for patients. These maximum hourly limits do not directly relate to the session, as all assessments, feedback and review services may need to be conducted over several shorter sessions if people fatigue and cannot complete each service in one session. PASC noted that these proposed fees seem disproportional to other consultation fees. No further justification of these fees has been provided.

Table 4 Proposed items and fees for CNA services by the applicant

Proposed Item	DVA Item (if avail.)	Item Description	Maximum Cost**
1	CL20*	<i>Neuropsychology Assessment</i> (Short 1-4 hours)	\$595.65
2	CL25*	<i>Neuropsychology Assessment</i> (Medium 4-6 hours)	\$893.48
3	CL30*	<i>Neuropsychology Assessment</i> (Long 6-8 hours)	\$1191.30
4	n/a	<i>Neuropsychology Feedback</i> (Standard 1-2 hours) Includes written report and recommendations specifically for the patient.	\$297.82
5	n/a	<i>Neuropsychology Feedback</i> (Extended 3-4 hours) Includes written report with management plan and detailed recommendations specifically for the patient.	\$595.65

Proposed Item	DVA Item (if avail.)	Item Description	Maximum Cost**
6	n/a	<i>Neuropsychology Review (Short 1-4 hours)</i> Includes reassessment as required, written report and recommendations.	\$595.65
7	n/a	<i>Neuropsychology Review (Medium 4-6 hours)</i>	\$893.48

DVA = department of veterans affairs

*From Neuropsychologists Schedule of Fees, November 2013, DVA

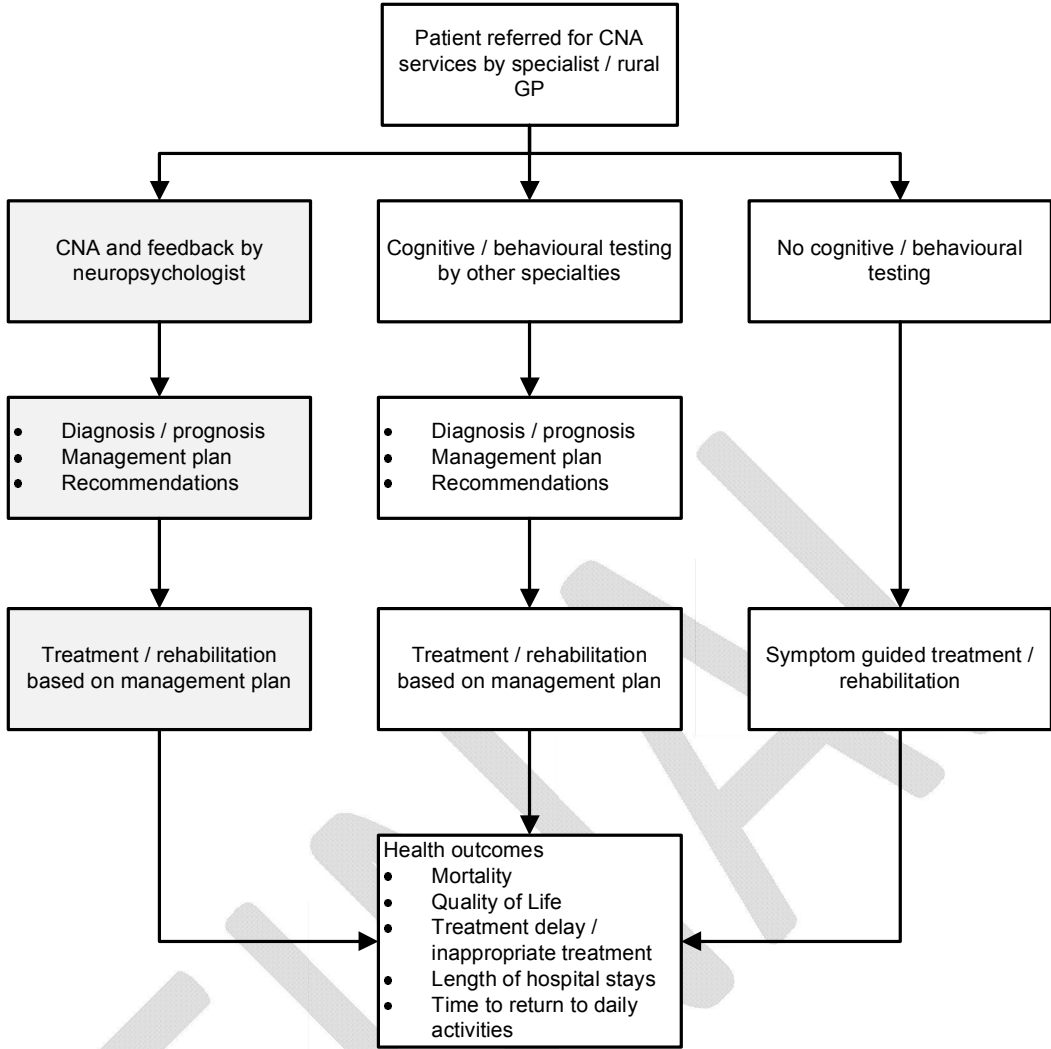
**All items are calculated without GST.

PASC recommended that bundles of tests should be defined for assessment time periods (short, medium, long). However, the applicant has indicated that it is very difficult to judge in advance how long a CNA will take, and needs to be based on the patient's individual needs.

9. Clinical Management Algorithm - clinical place for the proposed intervention

The clinical place for CNA services occurs at a point at which the patient's specialist (or rural GP) makes a clinical judgement that a CNA is necessary to assist with diagnosis, and/or to determine an appropriate management plan. The intervention (CNA services, grey boxes) is described below in a clinical management algorithm, alongside the comparators (testing by other specialties, no cognitive/behavioural testing). Other tests such as imaging (MRI, CT, functional imaging) or blood tests may be done either before or after CNA, depending on the situation and the patient's symptoms. CNA may be done to assess the functional capacity after an abnormal imaging result, or the patient may be referred for other tests if CNA shows cognitive or behavioural deficits. Please note that children will usually not receive cognitive/behavioural testing by other specialties (such as the MMSE), therefore the only pathways relevant in this population will be CNA and 'no cognitive/behavioural testing'.

Figure 1 Clinical management algorithm



CNA = clinical neuropsychology assessment; GP = general practitioner

10. Regulatory Information

Not applicable.

11. Decision analytic

Depending on the comparator, the outcomes assessed would either be financial (if CNA is compared to other funding sources), or safety, effectiveness and cost-effectiveness (when no testing or alternative testing is used as a comparator). The criteria for assessment of CNA services are defined through a description of the relevant population, intervention, comparator and outcomes (PICO), and described in Table 5 below.

The effectiveness of CNA services depends on whether it improves patient outcomes. This can be assessed by studies which directly investigate the impact of CNA on health outcomes, compared to one of the comparators (direct evidence). However, as this type of evidence is often lacking, a linked evidence approach should be used where key elements of the diagnostic-to-treatment pathway are linked. This includes evidence on diagnostic test performance (e.g. diagnostic yield), the therapeutic

efficacy (change in management), and the therapeutic effectiveness (impact of change in management on health outcomes). A linked evidence approach needs to be undertaken when there is no direct evidence available.

Table 5 Summary of PICO to define research question

Patients	Intervention	Comparator(s)	Outcomes to be assessed
Children or adults referred for neuropsychological assessment services	Clinical Neuropsychological Assessment services by a neuropsychologist <ul style="list-style-type: none"> • Assessment • Feedback • Review 	CNA paid for out-of-pocket	Financial impact
Adults referred for neuropsychological assessment services	Clinical Neuropsychological Assessment services by a neuropsychologist <ul style="list-style-type: none"> • Assessment • Feedback • Review 	Limited cognitive / behavioural assessment through other specialties No CNA (and symptom guided management)	<p>Safety:</p> <ul style="list-style-type: none"> • Psychological harms from CNA / no CNA (e.g. stress, anxiety, worrying) <p>Effectiveness:</p> <p>Direct evidence / therapeutic effectiveness</p> <ul style="list-style-type: none"> • Mortality • Quality of Life • Psychological health • Functioning <p>Diagnostic accuracy</p> <ul style="list-style-type: none"> • Diagnostic yield • Concordance analysis <p>Therapeutic efficacy</p> <ul style="list-style-type: none"> • Any management changes due to CNA • Avoidance of inappropriate treatment / investigations • Treatment delay • Length of hospital stays <p>Cost-effectiveness:</p> <ul style="list-style-type: none"> • Costs • Costs per quality adjusted life year • Costs per disability adjusted life year <p>Financial impact:</p> <ul style="list-style-type: none"> • Uptake of test by patients waiting in public system or otherwise not receiving CNA

CNA = clinical neuropsychology assessment

Proposed research questions:

1. What is the financial impact of listing clinical neuropsychological assessment (CNA) services for the assessment, feedback and review of patients (e.g. with neurodegenerative diseases, acquired brain injuries, paediatric or developmental disorders) on the MBS, as compared to patients receiving CNA through self-pay?

2. Are CNA services for the assessment, feedback and review of adult patients (e.g. with neurodegenerative diseases or acquired brain injuries), safe, effective and cost-effective compared with limited cognitive/behavioural assessments performed by other specialties?
3. Are CNA services for the assessment, feedback and review of adult patients (e.g. with neurodegenerative diseases, acquired brain injuries, paediatric or developmental disorders), safe, effective and cost-effective compared with no CNA, and symptom guided management?

12. Healthcare resources

There are no other resources co-administered with the intervention. The tests done during a CNA depend on the patient's symptoms and (suspected) disease or disorder. If CNA is compared to assessment by other specialties, the possible comparator consultations are shown in Table 2. The resources used to manage or treat patients after the intervention/comparator also depend on the disease/disorder and the patient's symptoms. CNA may be used as a gate keeping activity, e.g. if concerns are raised about the patient's functioning. If deficits in cognitive functioning are found, more detailed investigation may be done, such as blood tests, imaging tests or nerve conduction studies. On the other hand, it can also be the case that the results of blood tests and imaging studies lead to a referral for CNA services to assess functional capacity. As it depends on the situation of an individual patient which healthcare resources will be used with/without CNA, no resource table was included in the protocol.

If more people access CNA then there is likely to be a growth in demand for other specialty services, within and health and outside of it, if particular diagnoses are made. The impact of this is not ascertainable; because the range of patient presentations and diagnoses is likely to be very broad, it is uncertain how many *extra* services may be required as a result of recommendations of the CNA. However, there may also be a decrease in certain services or treatments on the basis of the results of the CNA.

Given that the unmet need for CNA services is currently unknown, the potential uptake of these services will need to be considered in light of which patients access the services and if their uptake is equitably distributed across socioeconomic groups; if CNA services are available to patients across regional and rural areas and not just in metropolitan centres; and, if the current workforce can meet potential demand for the services.

13. Appendix

Supplementary Table 1 Prevalence of paediatric and developmental disorders by level of restriction and sex, per cent of Australian population for relevant age group and sex, 1998 (AIHW 2004)

	Boys, 0-14 years		Girls, 0-14 years		Children, 0-14 years	
	'000	%	'000	%	'000	%
All disabilities/disorders						
Intellectual/learning	104.6	5.2	38.5	2.0	143.0	3.7
Psychiatric	30.4	1.5	13.2	0.7	43.6	1.1
Sensory/speech	80.0	4.0	39.9	2.1	119.9	3.1
All disabilities/disorders and severe or profound core activity restriction						
Intellectual/learning	58.7	2.9	24.3	1.3	83.0	2.1
Psychiatric	25.8	1.3	11.2	0.6	37.0	0.9
Sensory/speech	54.1	2.7	23.5	1.2	77.6	2.0
Main disability/disorder						
Intellectual/learning	87.1	4.4	25.7	1.3	112.9	2.9
Psychiatric	5.1	0.3	3.1	0.2	8.2	0.2
Sensory/speech	32.9	1.6	19.4	1.0	52.3	1.3
Main disability/disorder and severe or profound core activity restriction						
Intellectual/learning	45.9	2.3	14.6	0.8	60.4	1.5
Psychiatric	3.4	0.2	2.1	0.1	5.4	0.1
Sensory/speech	15.3	0.8	7.2	0.4	22.6	0.6

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