EXECUTIVE SUMMARY

IMeRSe – Indigenous Medication Review Service

This submission-based assessment examines the evidence to support listing of the *Indigenous Medication Review Service* (IMeRSe)[1] for funding by the Australian Government Department of Health. The service would be used in Aboriginal and Torres Strait Islander health settings to promote integrated multidisciplinary management of medication safety in primary care. The target population are Aboriginal and Torres Strait Islander people with the potential for medication-related problems (MRPs). We propose that the successful listing of the service in the target population and setting will lead to improved medication adherence and fewer MRPs.

[*redacted*]

ALIGNMENT WITH AGREED PICO CONFIRMATION

This submission-based assessment of IMeRSe addresses all of the PICO (population, intervention, comparator, outcomes) elements.

The PICO was not formally ratified by the PICO Advisory Sub-Committee (PASC).

The study protocol was ratified by the Pharmacy Trials Advisory Group, an Independent expert advisory committee who provided advice to the Australian Government Department of Health on the development and implementation of trials under the Pharmacy Trial Program.

PROPOSED MEDICAL SERVICE

The IMeRSe service is a six-step collaborative intervention that reflects a primary healthcare team approach involving: the consumer, Aboriginal Health Service staff (Aboriginal Health Worker [AHW] and/or Aboriginal Health Service [AHS] clinician), community pharmacist and a general practitioner (GP); each with their respective roles. AHWs led consumer engagement and supported a community pharmacist-led medication review with the consumer participant and when preferred, additional support person(s) (e.g. family). The process was finalised by a GP-led medication plan in consultation with the consumer, AHW and community pharmacist. This initial medication review process was referred to as Tier 1. Additional, structured, follow-up and monitoring could be provided over the following 6-month period (referred to as Tier 2) as required, and negotiated by the community pharmacist, consumer, AH, and GP as part of the medication plan tailored to individual needs.

IMeRSe is not currently funded in Australia.

[1] In this report the use of the term 'Indigenous Australians' refers respectfully to all Aboriginal and Torres Strait Islander people and acknowledges their rich traditions and heterogenous cultures.

PROPOSAL FOR PUBLIC FUNDING

As advised by the Pharmacy Trial Advisory Group, the PASC process has not been used.

There are three proposed items descriptors: one for community pharmacists, one for AHWs, and one for GPs, with additional proposed block funding to support cultural awareness training and clinical support for pharmacists providing the service.

Table 1 Proposed MBS Item Descriptors

A. Category M3 – Allied Health Services
Aboriginal and Torres Strait Islander medication review service (IMeRSe)
Participation by a **pharmacis**t in a culturally responsive medication management review with a consumer living in a community setting, in which the pharmacist, with the consumer's consent: (a) assesses and confirms the consumer is: i. a self-identified Aboriginal or Torres Strait Islander Australian; ii. aged 18 years or over; iii. at risk of medication-related problems (as identified by any treating health professional, or family member, or self-identified) including but not limited to: ▪ being diagnosed with at least one chronic condition, which is current, and/or is pregnant, and/or is within 2 years post partum; ▪ instability of health status and/or medication therapy; ▪ using high-risk medication(s); ▪ likelihood of compromised adherence; ▪ new therapeutic goals; ▪ potentially incomplete understanding of medication use; or ▪ failure to respond to treatment in an expected way (b) following assessment, undertakes a medication management review (Tier 1), at a location agreed upon by the consumer, in conjunction with a recognised support worker (AHW or other clinic staff), and family member or carer as requested by the consumer; (c) develops a written medication report for submission to the consumer's usual GP within 2 weeks of undertaking the medication review; (d) undertakes any follow-up (Tier 2) required by the consumer or GP, with up to 2 interactions in the subsequent 12 month period. For any particular consumer – applicable not more than once in each 12-month period, except if there has been a significant change in the consumer's condition or medication regimen requiring a new medication plan. Ineligible if a Domiciliary Medication Management Review (DMMR), Residential Medication Management Review (RMMR), or MedsCheck service has been provided in the previous 12 months. **Fee:** $ 222.77 **Benefit**: 100% = $222.77 First follow-up service **Fee:** $ 111.39 **Benefit:** 100% = $111.39 Second follow-up service **Fee:** $ 55.70 **Benefit:** 100% = $55.70 **Rural loading allowance** Up to [redacted] – to contribute to travel costs or the cost of locum hire as required, to allow participation by the pharmacist.
B. Category M3 – Allied Health Services
Aboriginal and Torres Strait Islander medication review service (IMeRSe)

Participation by an **Aboriginal Health Worker** (AHW) in a culturally responsive medication management review for a consumer living in a community setting, in which the AHW, in conjunction with a pharmacist, with the consumer's consent,

(a) assesses and confirms the consumer is:
   i. a self-identified Aboriginal or Torres Strait Islander Australian;
   ii. aged 18 years or over;
   iii. at risk of medication-related problems (as identified by any treating health professional, or family member, or self-identified) including but not limited to:
      - being diagnosed with at least one chronic condition, which is current, and/or is pregnant, and/or is within 2 years post partum;
      - instability of health status and/or medication therapy;
      - using high-risk medication(s);
      - likelihood of compromised adherence;
      - new therapeutic goals;
      - potentially incomplete understanding of medication use; or
      - failure to respond to treatment in an expected way

(b) following assessment, participates in a medication management review, at a location agreed upon by the consumer, in conjunction with the AHW (or other clinic staff), and family member or carer as requested by the consumer;

(c) participates in a subsequent review with the consumer and GP and assists with finalisation of a medication plan for the consumer, as requested by the consumer;

(d) participates in any follow-up (Tier 2) required by the consumer or GP, with up to 2 interactions in the subsequent 12-month period.

For any particular consumer – applicable not more than once in each 12 month period, except if there has been a significant change in the consumer's condition or medication regimen requiring a new medication plan. Ineligible if a Domiciliary Medication Management Review (DMMR), Residential Medication Management Review (RMMR), or MedsCheck service has been provided in the previous 12 months.

Fee: $50.00 **Benefit:** 100% = $50.00

First follow-up service

Fee: $25 **Benefit:** 100% = $25

Second follow-up service

Fee: $12.50 **Benefit:** 100% = $12.50

C. Category A17 – Domiciliary and residential medication management reviews

Aboriginal and Torres Strait Islander medication review service (IMeRSe)

Participation by a **general practitioner** (GP) in a culturally responsive medication management review for a consumer living in a community setting, in which the pharmacist, with the consumer's consent,

(a) assesses and confirms the consumer is:
   i. a self-identified Aboriginal or Torres Strait Islander Australian;
   ii. aged 18 years or over;
   iii. at risk of medication-related problems (as identified by any treating health professional, or family member, or self-identified) including but not limited to:
      - being diagnosed with at least one chronic condition, which is current, and/or is pregnant, and/or is within 2 years post partum;
      - instability of health status and/or medication therapy;
      - using high-risk medication(s);
      - likelihood of compromised adherence;
      - new therapeutic goals;
      - potentially incomplete understanding of medication use; or
      - failure to respond to treatment in an expected way

(b) following assessment and submission of the medication management review by the pharmacist, develops a medication plan in consultation with the consumer, including the AHW, and family member or carer as appropriate, within 2 weeks of receiving the medication review; and

(c) submits the medication plan to the pharmacist who undertook the medication review, with suggestions for further follow up as deemed appropriate;

(d) reviews any documented follow-up actions submitted by the pharmacist (up to 2 interactions in the subsequent 12 month period) and updates the medication plan as required.

For any particular consumer – applicable not more than once in each 12-month period, except if there has been a significant change in the consumer's condition or medication regimen requiring a new medication plan. Ineligible if a Domiciliary Medication Management Review (DMMR), Residential Medication Management Review (RMMR), or MedsCheck service has been provided in the previous 12 months.

Fee: $ 75.05 **Benefit:** 100% = $75.05

D. Additional block funding to support implementation in Years 1-5

Aboriginal and Torres Strait Islander medication review service (IMeRSe)

To support the implementation of IMeRSe for Years 1-5, the following services will be provided, subject to the identification of a suitable provider:

(a) provide cultural capability training for pharmacists, pharmacy staff and mainstream health clinic staff involved in the delivery of IMeRSe, consisting of:

  i. an online training module (already developed and accredited); and

  ii. a face-to-face or video-conference interactive session with an appropriate provider of cross-cultural training;

(b) an ongoing support line for cultural mentoring of any health practitioners or support staff involved in delivering the IMeRSe service, to be provided by a suitably qualified Aboriginal and Torres Strait Islander person/people;

(c) an ongoing clinical support line for pharmacists, provided by a clinical pharmacist with extensive medication review expertise;

(d) development and moderation of a secure chat line for pharmacists and other health professionals involved in the delivery of IMeRSe;

(e) documentation of all services provided for the purpose of external evaluation.

Total: [*redacted*] ([*redacted*] per year for 5 years)

POPULATION

The proposed population is:

i. self-identified Aboriginal or Torres Strait Islander Australians;
ii. aged 18 years and over and living in the community;
iii. at risk of medication-related problems (as identified by any treating health professional, family member or self-identified) including but not limited to:
    - being diagnosed with at least one chronic condition and/or is pregnant and /or is within 2 years post-partum;
    - instability of health status and/or medication therapy;
    - using high-risk medication(s);
    - likelihood of compromised adherence;
    - new therapeutic goals;
    - potentially incomplete understanding of medication use; or
    - failure to respond to treatment in an expected way.

It is proposed that eligible individuals can access IMeRSe once per year.

Data from the National Health Survey of Australia was used to estimate the likely prevalent population, based on age, having at least one chronic condition and taking five or more prescription or complementary medicines. This will overestimate the eligible population as the subjective criteria of "being at risk of medication-related problems" cannot robustly be applied. In the submission, the estimated eligible population is 96,597 ~~(Table 29)~~.

COMPARATOR DETAILS

The comparator is usual care, which was the comparator ratified for the IMeRSe Feasibility Study protocol by the Trials Advisory Group (TAG). Usual care can include ad-hoc medication management advice by a range of health practitioners involved in the consumers care, including pharmacists, doctors, nurses and AHWs. Usual care does not include other formal medication management review services, such as a Domiciliary Medication Management Review (DMMR), Residential Medication Management Review (RMMR), Diabetes MedsCheck or MedsCheck. This was an exclusion criterion for participation in the IMeRSe feasibility study and is included as a restriction within the relevant item descriptors.

CLINICAL MANAGEMENT ALGORITHM(S)

If listed, it is likely that IMeRSe would partially replace usual care for the eligible population, that is, some unstructured medication advice would be potentially replaced by the structured IMeRSe. Listing of IMeRSe does not remove the possibility that Aboriginal and Torres Strait Islander people will not access ad-hoc medication advice in addition to IMeRSe ~~(Figure 1)~~.

KEY DIFFERENCES IN THE DELIVERY OF THE PROPOSED MEDICAL SERVICE AND THE MAIN COMPARATOR

IMeRSe is a structured medication management review service, requiring the pharmacist and support staff involved in delivery to participate in cross-cultural training and optional use of the *Stay Strong*

Plan as a motivational interviewing, problem identification and goal setting technique. Consumers have the choice of where the *Medicines Talk* (medication review) service occurs (e.g. at the AHS, in the pharmacy or in the home), as well as the choice to include an AHW, and family member(s) or carer in this process to help build a relationship with their pharmacist. IMeRSe does not require referral from the GP, allowing for opportunistic identification of the need for medication review by other health practitioner(s) or support person(s) within the team and decreasing the administrative burden for GPs. The process of requiring GPs to finalise a medication plan with the consumer, after considering the medicines report prepared by the pharmacist, and provide the consumer's *Medicines Plan* to the pharmacist, promotes two-way communication between pharmacists and GPs. Reimbursement of follow-up services provided by the pharmacist promotes continuity of care and relationship building between the pharmacist and consumer.

In comparison, usual care currently includes no formal process of medication review. Medication advice may be provided in an ad-hoc manner by any health practitioner involved in the consumer's care. Pharmacists are not routinely available to consumers at AHSs.

CLINICAL CLAIM

Evidence from the IMeRSe Feasibility Study shows that the intervention has [*redacted*]..

The clinical claim has not been revised by PASC as advised by the Pharmacy TAG.

APPROACH TAKEN TO THE EVIDENCE ASSESSMENT

A systematic review of published and unpublished literature was undertaken.

Health literature was searched to identify relevant studies, including systematic reviews, published during the period 1946 to August 2020. Searches were conducted using Medline (Ovid), Scopus, CINAHL Complete (EBSCO) and the Cochrane Library (~~Table 8 and Appendix A~~). Attempts were also made to source unpublished or grey literature from published references, higher degree research theses and partner organisations in the IMeRSe Feasibility Study (NACCHO and Pharmacy Guild of Australia).

CHARACTERISTICS OF THE EVIDENCE BASE

Only one study that met the search criteria was found; that was the IMeRSe Feasibility Study ~~(Appendix B).~~ The study was undertaken in the population of interest and in relevant Australian healthcare settings. The feasibility study was designed to inform a future randomised controlled trial RCT); as such the study objectives included measuring feasibility and implementation success as well as clinical outcomes and feasibility of adopted measures. Inherent with the design of a feasibility study, it was likely underpowered [*redacted*]. The study also collected a range of consumer-relevant secondary outcomes which showed [*redacted*].

The study only included one of nine included sites where consumers accessed a mainstream general practice, rather than an AHS. This is important as not all Aboriginal and Torres Strait Islander peoples

have access to AHSs. As such, there is limited evidence of the success in mainstream general practice settings.

RESULTS

Safety

No safety concerns were identified during the IMeRSe Feasibility Study. [*redacted*]

[*redacted*] no complaints about the intervention itself were received. No other safety concerns were identified during the IMeRSe Feasibility Study.

Effectiveness

Results from the IMeRSe Feasibility Study showed positive, clinically meaningful, outcomes for participants. The primary outcome showed [*redacted*]. By definition, these pre-specified clinical indicators were selected on the basis that they are likely to increase the probability of experiencing a hospital admission if left unresolved. The realisation of serious MRPs are potentially preventable medication-related hospitalisations (PPMRHs). [*redacted*]).

Other consumer-relevant secondary outcomes showed [*redacted*].

Overall, the evidence suggests that participants in the IMeRSe Feasibility Study felt [*redacted*].

The summary of key findings is shown in Table 2.

Table 2 Balance of Clinical Benefits and Harms of IMeRSe, Relative to Usual Care, and as Measured by the Critical Patient-Relevant Outcomes in the Key Studies

Outcomes	Participants (studies)	Quality of evidence (GRADE) a	Incidence rate ratio (95%CI)	Pre rate/score (95%CI/SD)	Post rate/score (95%CI/SD)	Comments
Serious medication related problems (count/rate)	IMeRSe (2020), n=207	⊕⊕⊕⊙	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Potentially preventable medication-related hospitalisations (count/rate)	IMeRSe (2020), n=207	⊕⊕⊕⊙	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Medication adherence (MPR)	IMeRSe b (2020), n=599	⊕⊕⊕⊙		[*redacted*]	[*redacted*]	[*redacted*]
Empowerment (GEM)	IMeRSe (2020), n=96	⊕⊕⊕⊙		[*redacted*]	[*redacted*]	[*redacted*]

a GRADE Working Group grades of evidence [1]
b n = 599 is the number of paired comparisons for a particular medicine and individual from 207 participants with available data.
GEM=Growth and Empowerment; MPR=medication possession ratio; CI=confidence interval; SD=standard deviation
⊕⊕⊕⊕ **High quality:** We are very confident that the true effect lies close to that of the estimate of effect.

⊕⊕⊕⊙ **Moderate quality:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
⊕⊕⊙⊙ **Low quality:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
⊕⊙⊙⊙ **Very low quality:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

On the basis of the benefits and harms reported in the evidence base (summarised above), **it is suggested that, relative to usual care, IMeRSe has** [*redacted*].

TRANSLATION ISSUES

No translation issues of the clinical evidence were identified, and this is not presented. This was a pragmatic study undertaken in Australia with the eligible population in relevant healthcare settings.

ECONOMIC EVALUATION

The clinical evaluation suggested that, relative to usual care, IMeRSe has [*redacted*] based on the evidence profile given in Appendix C. It was therefore decided that a cost-consequence analysis would be undertaken for the economic evaluation (Table 3).

A cost consequence analysis was undertaken to estimate the cost per serious MRP avoided. A trial-based evaluation with a one-year time horizon, based on the results from the IMeRSe Feasibility Study, is presented using the pre-intervention period as the usual care comparator. An Australian government perspective was chosen for the base case, with a whole of government perspective in sensitivity analyses.

Table 3 Summary of the Economic Evaluation

Perspective	Commonwealth Government (base case) and Commonwealth and state governments (sensitivity analysis)
Comparator	Usual care
Type of economic evaluation	Cost-consequence
Sources of evidence	IMeRSe Feasibility Study
Time horizon	6 months (in-trial analysis)
Outcome	Serious medication related problems avoided
Methods used to generate results	Trial based
Discount rate	Not applicable (time horizon <12 months)
Software packages used	Excel

The overall costs and outcomes, and incremental costs and outcomes as calculated for the intervention and comparator in the model, and using the base case assumptions, are shown in Table 4. There was some [*redacted*]. It is important to note that the source of evidence for this application, the IMeRSe Feasibility Study, was not designed to provide RCT evidence of effectiveness and cost effectiveness.

Table 4 Cost Consequence Analysis for One Serious Medication-Related Problem Avoided

Scenario	Pre-rate (95%CI)	Post-rate (95%CI)	Difference (95% CI)	p-value	Cost per person	Cost per MRP avoided	Assumption
Base case	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	IMeRSe cost at MSAC fees; no cost usual care

MRP=medication-related problems; CI=confidence interval; ED=emergency department
Note: The rate is reported as a rate per person per 6 months, estimated using a mixed effects Poisson model. [*redacted*]

The modelled results were most sensitive to the effect of IMeRSe [*redacted*].

Table 5 Key Drivers of the Economic Model

Description	Method/Value	Impact

ESTIMATED EXTENT OF USE AND FINANCIAL IMPLICATIONS

An epidemiological approach has been used to estimate the financial implications of the introduction of IMeRSe. The financial implications to the MBS resulting from the proposed listing of IMeRSe are summarised in Table 6.

Table 6 Total Costs to the MBS Associated with IMeRSe

	2021-22	2022-23	2023-24	2024-25	2025-26
Block funding	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Number of services - urban	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Sub-total cost urban	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Number of services - rural	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Sub-total cost rural	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Number of services - remote	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Sub-total cost remote	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Total services	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]
Total cost	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]	[*redacted*]

CONSUMER IMPACT SUMMARY

As the PICO was not formally ratified, there was no public consultation period prior to PICO confirmation. However, extensive qualitative research was undertaken with consumers during the IMeRSe Feasibility Study.

Consumer participants spoke positively about [*redacted*].

OTHER RELEVANT CONSIDERATIONS

Equitable access to health care

The IMeRSe intervention was shown to provide culturally responsive, strengths-based, medication review services, integrated into a range of primary health care settings that addressed existing barriers

to the uptake of existing medication management services. [*redacted*] Currently, no culturally responsive medication review service is available for Indigenous Australians, who typically endure worse health than other Australians.

Equitable access to quality health care, which is responsive to need and provides value for money, are key tenets of the National Medicines Policy.

Comparison with existing medication management review services

Whilst both HMRs and IMeRSe are comprehensive medication review services performed by registered pharmacists, IMeRSe is an innovative service that specifically addresses the existing barriers for Indigenous people to access medication management services: including the requirement for it to be held at home, to be referred by a GP, and the lack of reimbursement for inclusion of Indigenous support staff.

From a consumer perspective the biggest difference lies in the cultural safety aspects; inseparable from IMeRSe delivery. This is where IMeRSe departs from traditional medication review services such as HMR in that it required pharmacists and Aboriginal Health Services to establish and maintain quality relationships and share workflow to identify, refer and provide medication review for their consumers. Pharmacists involved in IMeRSe delivery completed cross-cultural training which focused on: cultural capability, confidence, and skills for working effectively with Indigenous people and their communities; and use of the Stay Strong Plan as a motivational interviewing, problem solving, and goal setting technique developed for Indigenous Australians. This was followed by mentoring (for clinical and cultural support) and ongoing cross-cultural seminars to support positive health outcomes and consumer experiences. Pharmacists delivering IMeRSe were not required to be HMR accredited.

Pharmacy workforce considerations

In the IMeRSe Feasibility Study pharmacists were trained to deliver a culturally responsive service not currently part of existing medication management services. This training equipped pharmacists with the skills necessary to successfully engage Aboriginal and Torres Strait Islander community members and overcome reported barriers to accessing other existing medication management services. [*redacted*]

Whilst other medication management services exist (e.g. HMRs), there are both cultural and geographic barriers to service access. Most recently this was highlighted in research which mapped national polypharmacy rates, as a proxy for population need for medication review services, identifying that there were insufficient accredited pharmacists to provide medication review services in rural and remote Australia [51].

Additionally, special consideration of small pharmacies, particularly one-pharmacist pharmacies, is required for the IMeRSe service to be feasibly delivered in rural and remote areas. Financial incentives that can be used to cover the cost of locum support and travel are required to provide pharmacists with sufficient time and resources to undertake medication review services in these areas. Making the

requirements for use of such financial incentives overly prescriptive however, may reduce the ability of local health networks to implement local solutions to service delivery barriers.