Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1498 – Serum Soluble Transferrin Receptor Testing

Applicant: **The Royal College of Pathologists of Australasia (RCPA)**

Date of MSAC consideration: **MSAC 74th Meeting, 22-23 November 2018**

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, visit the MSAC website

1. Purpose of application

An application requesting Medicare Benefit Schedule (MBS) listing for a test for soluble transferrin receptor (sTfR) to aid in differentiating between iron deficiency anaemia (IDA) and anaemia of chronic disease (ACD) in patients with serum ferritin levels of 30-100 µg/L (or 20-100 µg/L in children) and transferrin saturation (TSAT) < 30% was received from the Royal College of Pathologists Australasia (RCPA).

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, MSAC did not support public funding for serum soluble transferrin receptor testing, as the clinical benefit and diagnostic accuracy of the test in the proposed management algorithm is uncertain and difficult to quantify, and these uncertainties flowed to the economic analysis.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted that the MBS Review Taskforce (the Taskforce) has recently examined and made recommendations on the existing MBS items relating to iron studies, so that the default test for iron deficiency for most patients is serum ferritin. MSAC noted that the Taskforce report is currently undergoing consultation.

MSAC noted that the clinical claim is that sTfR testing will aid in the differentiation between IDA and ACD in patients who meet the following criteria.

- confirmed diagnosis of anaemia; and
- serum ferritin levels of 30–100 µg/L (or 20–100 µg/L for children); and
- TSAT less than 30%.

As a consequence, sTfR testing will allow:

- identification of patients who will not respond to iron therapy; and
- timely and targeted investigations to diagnose underlying disease.

As management differs between patients with IDA and those with ACD, it is important to correctly diagnose anaemic patients in order to guide appropriate clinical management.

MSAC noted that diagnosis of IDA requires the patient to be anaemic (low haemoglobin) and iron deficient and the proposed eligibility for sTfR testing requires a low TSAT (performed as part of iron studies). So for the patients proposed for sTfR testing, haemoglobin, ferritin and TSAT results will already be available.

MSAC noted that sTfR testing is performed on the same blood sample used for haemoglobin concentration and serum ferritin level testing. Therefore, there are no additional safety issues that arise relating to additional sample collection.

MSAC noted the paucity of epidemiological data on the prevalence of anaemic patients with ferritin levels of 30–100 µg/L (or 20–100 µg/L in children) and TSAT of less than 30%. Data provided by the RCPA Working Group estimated this prevalence to be 3.7%; however, these data were sourced from a single large community- and hospital-based practice and estimated to include about 10% of all Medicare Pathology activity over 1 month.

MSAC noted that, as there was no direct evidence to assess sTfR testing in anaemic patients with ferritin levels of 30–100 µg/L (and 20–100 µg/L in children) and a TSAT <30%, a linked evidence approach was adopted. One study was identified that included an analysis of the diagnostic accuracy of sTfR testing in adults with anaemia who had serum ferritin levels of 10–100 µg/L. This single study was included in the assessment because it reported the diagnostic accuracy of sTfR and ferritin separately in a range of ferritin levels close to that specified in the PICO. The reference standard used was a composite of three criteria, each of uncertain accuracy, and also included the index test; therefore, the study was at risk of verification and incorporation bias. Coupled with poor reporting of patient selection and uncertainty of whether a case-control design was avoided, this led to the study being assessed as being at a high risk of bias.

MSAC noted that, given the lack of evidence for the population of anaemic patients already determined to have ferritin levels of 30–100 µg/L (or 20–100 µg/L for children) and a TSAT of <30%, it is suggested that, relative to ferritin testing or iron studies, sTfR testing and associated interventions has uncertain effectiveness.

Additionally, MSAC noted that, for the population of anaemic adults already determined to have ferritin levels of 10–100 µg/L, it is suggested that sTfR testing and associated interventions have uncertain safety and uncertain effectiveness relative to ferritin testing or iron studies.

MSAC noted that a cost-consequence model was not created because of the paucity of evidence for, and the significant uncertainties surrounding, the complex diagnostic and

treatment pathways in an extremely heterogeneous patient population, with subsequent unacceptable levels of uncertainty of any cost and probability estimations.

MSAC noted that patients diagnosed with ACD will undergo further investigations to determine the underlying cause of the anaemia. Because ACD is associated with a range of conditions (including rheumatoid arthritis, cancer, infections, chronic kidney disease and heart failure), many possible investigation(s) may be ordered. Identifying the relevant investigation(s) depends on many factors, including patient demographics, clinical history, and results of examination and/or other tests. Therefore, estimates of costs and probabilities of additional investigations and associated treatment(s) were not able to be adequately quantified.

MSAC noted an uncertain volume of use per year. Utilisation estimates were based on a single large practice that estimated prevalence of anaemic patients with ferritin levels of 30–100 µg/L (or 20–100 µg/L in children) and TSAT of less than 30%. at 3.7%; however, the estimate in the PICO confirmation was 5%. An increase in the rate from 3.7% to 5% increases costs in 2018 from $9.7 million to $13.1 million.

MSAC noted that the applicant was unable to provide any additional information before the MSAC meeting, in response to the comments from ESC.

4. Background

MSAC has not previously considered this application for sTfR testing.

sTfR testing is not currently funded or reimbursed in the private setting in Australia.

5. Prerequisites to implementation of any funding advice

Serum soluble transferrin receptor (sTfR) testing is an in-vitro diagnostic assay which is subject to TGA processes and laboratory validation. There are several commercially available sTfR assays.

Testing would be delivered by approved pathology practitioners in accredited pathology laboratories.

6. Proposal for public funding

The original proposed item descriptor for public funding is summarised in Table 1.

Table 1 Proposed MBS item descriptor

Category 6 – Group P2 – PATHOLOGY SERVICES
Serum soluble transferrin receptor - quantitation, in patients with anaemia and normal or greater than normal serum ferritin
MBS Fee: $45.00

The proposed alternative item descriptor is summarised in Table 2, noting that this item descriptor has not been ratified either by the applicant or PASC.

Table 2 Proposed alternative MBS item descriptor

Category 6 – Group P2 – PATHOLOGY SERVICES
Serum soluble transferrin receptor - quantitation, in patients with a confirmed diagnosis of anaemia with serum ferritin levels of 30-100 µg/L (or 20-100 µg/L in children) and transferrin saturation of less than 30%. This service to be provided by pathologists.
MBS Fee: $45.00

7. Summary of Public Consultation Feedback/Consumer Issues

Two responses were received in the consultation feedback. Overall, both responses were positive, noting:

- the proposed intervention is now an established test for the investigation of anaemia; and
- the benefits of measuring sTfR are largest if the assay is limited to patients who have co-existent acute inflammation (as evidenced by elevated c-reactive protein (CRP) levels) or co-existent anaemia of chronic disease (as determined by the requesting clinician).

However, one response indicated that 'while there is significant clinical benefit we do not believe that every third request for iron studies or ferritin requires sTfR'.

8. Proposed intervention's place in clinical management

Anaemia is a condition associated with reduction in the concentration of red blood cells or haemoglobin, resulting in lowered ability of the blood to carry oxygen. The two most common forms of anaemia are IDA and ACD (or anaemia of chronic inflammation).

The proposed test is an in-vitro diagnostic assay, which quantifies the levels of sTfR in serum and/or plasma samples. sTfR is a marker of iron deficiency when tissue iron stores are depleted in the absence of other causes of abnormal erythropoiesis. sTfR levels are not affected by inflammation, thus sTfR testing has a role in differentiating between patients with IDA (when sTfR is increased) and/or ACD (when sTfR is normal).

The proposed test is expected to be provided in addition to prior tests used in the diagnosis of anaemia (IDA and/or ACD), which include full blood count (MBS item 65070), ferritin levels (MBS item 66593), and iron studies (MBS item 66596) in the proposed population (see proposed clinical management algorithm for sTfR testing in Figure 1).

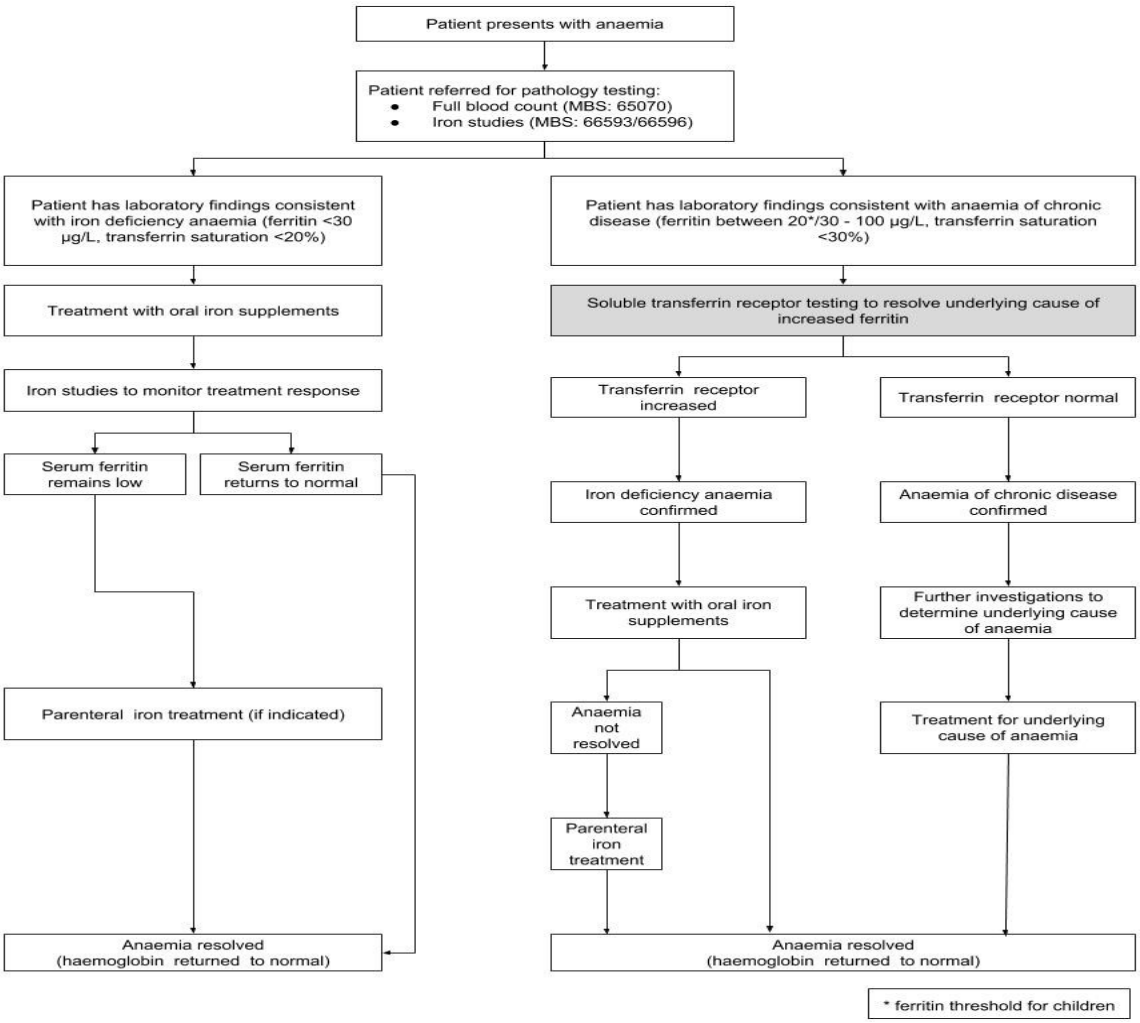

Figure 1 Clinical management algorithm for the proposed new test relative to current clinical practice

The application stated that at present (without sTfR testing), patients with anaemia and serum ferritin levels of 30-100 µg/L (or 20-100 µg/L in children) and a TSAT < 30% are considered to have ACD and are managed as such. The application stated that some of these patients may have IDA or IDA coexisting with ACD and may miss out on appropriate management and/or have treatment delayed and/or undergo unnecessary additional invasive investigations.

9. Comparator

The proposed comparators for patients with anaemia are the following

- Ferritin alone vs ferritin with sTfR or
- Iron studies (consisting of serum iron, transferrin or iron binding capacity, and ferritin) vs iron studies studies plus sTfR.

10. Comparative safety

The application proposed that no additional safety issues arise relating to additional sample collection as the sTfR testing is conducted on the same blood sample used for haemoglobin concentration, serum ferritin, and iron study testing.

No direct evidence was identified on changes in morbidity or mortality related to the use of sTfR testing in the specified population.

No direct evidence was identified on changes in the use of invasive investigations related to the use of sTfR testing in the specified population.

11. Comparative effectiveness

There was no direct evidence to assess sTfR testing in anaemic patients with ferritin levels of 30–100 µg/L (and 20–100 µg/L in children) and a TSAT <30%; a linked evidence approach was adopted.

Diagnostic performance

The application identified one study by Shin, Kim et al. (2015) which reported the comparative accuracy of sTfR testing over ferritin in diagnosing IDA and/or ACD in a subgroup of 107 patients (29.2% of patients overall) with anaemia and serum ferritin levels between 10-100 µg/L.

Table 3 Summary statistics for sTfR (and sTfR/log ferritin) compared to ferritin level alone, against reference standard*

Accuracy (1 study)	**sTfR** *(n=107)*	**sTfR/log ferritin** *(n=107)*	**Ferritin** *(n=107)*
Sensitivity, % [95% CI]	0.85 [0.71-0.94]	0.87 [0.74-0.95]	0.89 [0.76-0.96]
Specificity, % [95% CI]	0.90 [0.80-0.96]	0.97 [0.89-1.00]	0.77 [0.65-0.87]
Positive predictive value, % [95% CI]	0.87 [0.74-0.94]	0.95 [0.84-0.99]	0.75 [0.62-0.84]
Negative predictive value, % [95% CI]	0.89 [0.80-0.93]	0.91 [0.86-0.96]	0.90 [0.79-0.96]

Abbreviations: sTfR=serum soluble transferrin receptor; CI = confidence interval

* IDA was defined as:
1. serum ferritin levels <15 µg/L in males and <10 µg/L in females; or
2. serum ferritin <100 µg/L and transferrin saturation (TSAT) <15%, with elevation of sTfR or reduction in hepcidin; or
3. serum ferritin <200 µg/L (with increased CRP) and microcytic hypochromic anaemia responsive to the therapeutic trial of iron (i.e., more than 10% increase in mean cell volume [MCV] and mean cell Hb concentration [MCHC] within 3 weeks of iron supplementation).

Note: n was corrected (*italics*) during critique

Therapeutic efficacy (change in management)

No evidence was identified regarding therapeutic efficacy.

Therapeutic effectiveness (health benefit from change in management)

The characteristics of the proposed population are highly uncertain and heterogeneous: no evidence was identified that sufficiently described the population in terms of presentation, symptoms and signs, patient characteristics (including age, gender, past medical history, family history, risk factors), clinical suspicion, and findings from other investigations. Furthermore, existing management strategies are uncertain and likely variable, for example, which patients are given a therapeutic trial of iron as a diagnostic strategy or while waiting for other test results; or, what additional investigations would be ordered and under what circumstances.

Therefore, it is not possible to adequately quantify any health benefit from a change in management from sTfR testing (relative to proposed comparators).

Summary of linked evidence

Compared with ferritin testing alone, sTfR (and the sTfR/log ferritin ratio) identified fewer patients with IDA (with or without ACD) but identified more patients with ACD alone (Table 4).

Table 4 **Summary of findings for the diagnostic accuracy of sTfR and sTfR/log ferritin, relative to ferritin alone, in adult anaemic patients known to have ferritin levels between *10-100 µg/L*, with assumed pre-test probability (prevalence) of 43% from Shin, Kim et al. (2015)**

Outcomes	Participants	Quality of evidence [a]	No. per 1000 patients with ferritin alone	No. per 1000 patients with sTfR	No. per 1000 patients with sTfR/log ferritin	Comments
True positives	k=1 ; n=46	⊕⊙⊙⊙ VERY LOW	383 (331 to 409)	366 (310 to 404)	374 (318 to 409)	Patients correctly classified as having IDA±ACD with likely benefit from earlier diagnosis and treatment of IDA and uncertain benefit/harm from avoiding investigations (if any) for known or suspected comorbidity.[b]
True negatives	k=1 ; n=61	⊕⊙⊙⊙ VERY LOW	439 (371 to 490)	513 (456 to 542)	553 (507 to 570)	Patients correctly classified as having ACD alone with possible benefit from earlier additional investigations and/or treatment (if any) for known or suspected comorbidity and avoidance of iron therapy.[b]
False positives	k=1 ; n=46	⊕⊙⊙⊙ VERY LOW	131 (80 to 199)	57 (28 to 114)	17 (0 to 63)	Patients incorrectly classified as having IDA±ACD with uncertain harm from treatment of IDA and uncertain benefit/harm from delayed investigations and/or treatment for comorbidity.[b]
False negatives	k=1 ; n=61	⊕⊙⊙⊙ VERY LOW	47 (21 to 99)	64 (26 to 120)	56 (21 to 112)	Patients incorrectly classified as having ACD alone with possible detriment from delayed treatment of IDA and uncertain benefit/harm from additional investigations and/or treatment for comorbidity.[b]
Inconclusive results	k=1 ; n=107	None reported	NA	NA	NA	NA
Harms	k=1 ; n=107	None reported	NA	NA	NA	NA

Abbreviations: sTfR=serum soluble transferrin receptor; k=number of studies; n=number of participants; IDA=iron deficiency anaemia; ACD=anaemia of chronic disease; NA=not applicable

[a] GRADE Working Group grades of evidence (Guyatt, Oxman et al. 2013)

⊕⊕⊕⊕ **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.

[b] this is all contingent on multiple factors including how the patient presents, what symptoms and signs are elicited, patient characteristics (including age, gender, past medical history, family history, risk factors), clinical suspicion, and findings from other investigations.

The application clinical evaluation suggested that, relative to ferritin testing or iron studies, sTfR testing (and the sTfR/log ferritin ratio) and associated interventions have uncertain safety and uncertain effectiveness.

12. Economic evaluation

The application stated that an economic evaluation was not conducted because of the significant uncertainties surrounding the complex diagnostic and treatment pathways with subsequent unacceptable levels of uncertainty of any cost and probability estimates.

13. Financial/budgetary impacts

An epidemiological approach was used to estimate the financial implications of the introduction of the proposed public funding of sTfR testing based on the prevalence estimates reported from a single laboratory.

The direct MBS cost of the proposed listing in 2018 of $9.6 million rising to $11.3 million in 2021. When the additional cost of switching from ferritin quantitation to iron studies is included, the cost rises to $18.6 million in 2018 and $21.8 million is 2021 (Table 5). The CA stated that the estimates are based on the 85% rebate, but it is not known how many tests would be undertaken in hospital, nor how many patients are likely to have reached the Medicare Safety Net. The estimates are uncertain as the clinical pathway is heterogeneous and uptake of the test is unknown.

Table 5 Total costs to the MBS associated with sTfR testing

	2017	2018	2019	2020	2021
Direct cost of sTfR testing					
Number of services	261,347	253,030	267,229	281,428	295,626
Sub-total cost	$9,996,516	$9,678,410	$10,221,508	$10,764,605	$11,307,703
Incremental cost of additional iron studies					
Number of services	668,361	676,326	714,237	752,361	795,332
Additional incremental cost	$8,287,676	$8,386,446	$8,856,544	$9,329,279	$9,862,121
Total cost	$18,284,193	$18,064,856	$19,078,052	$20,093,885	$21,169,824

Abbreviations: MBS = Medicare Benefits Schedule; sTfR=serum soluble transferrin receptor

14. Key issues from ESC for MSAC

ESC key issue	ESC advice to MSAC
The clinical pathway	Some guidelines recommend use of sTfR testing in a slightly different pathway to that in the proposed clinical management algorithm.
Trial data	There is no direct evidence in the proposed population, and very limited and biased evidence about the test's effectiveness and applicability.
Test methodology	There is limited evidence of standardisation.
Heterogeneous population	There is no outcome or clinical utility data due to the heterogeneity of the population with chronic disease in terms of ages, conditions and outcomes.
Uncertainty in evidence	Overall, there is a need to develop models based on more defined pathways, if possible.
No conclusions on cost-effectiveness	An economic evaluation was not conducted because of the significant uncertainties surrounding the complex diagnostic and treatment pathways, with subsequent unacceptable levels of uncertainty of any cost and probability estimates.
Budget implications are uncertain	Estimates of budget impact are uncertain for a number of reasons (e.g. heterogeneous clinical pathway; unknown values for test uptake, inpatient tests and exclusion of costs of services related to ACD). However, because of the high number of iron studies tests performed, the potential implications for the MBS budget are significant. The impact on the PBS (for iron) and hospital system were not considered.

Abbreviations: ESC = Evaluation Sub-Committee; MSAC = Medical Services Advisory Committee; sTfR = serum soluble transferrin receptor; ACD = anaemia of chronic disease; PBS = Pharmaceutical Benefits Scheme; MBS = Medicare Benefits Schedule

ESC discussion

ESC noted that the original descriptor was considered not restrictive enough to conform with the PICO, so a new descriptor was proposed in the contracted assessment. Note that this item descriptor has not been ratified either by the applicant or PASC.

ESC noted that there are currently two clinically relevant MBS items relating to iron studies: 66593 (serum ferritin) and 66596 (iron studies). Neither of these have specific eligibility requirements or restrictions.

ESC noted that some guidelines would place sTfR testing at a different place in the clinical pathway to what is proposed in the clinical management algorithm in the application.
ESC noted that there is a paucity of epidemiological data reporting on the prevalence of anaemic patients with ferritin levels of 30–100 µg/L (or 20–100 µg/L in children) and TSAT of less than 30%; however, data were provided by the RCPA Working Group. ESC noted that these data were sourced from a single large community and hospital-based practice and estimated to include about 10% of all Medicare Pathology activity over 1 month. The prevalence estimated from that data was 3.7%. However, the estimate in the PICO confirmation was 5%.

ESC noted that, as there was no direct evidence to assess sTfR testing in anaemic patients with ferritin levels of 30–100 µg/L (and 20–100 µg/L in children) and a TSAT <30%, a linked evidence approach was adopted. ESC noted that one study was identified (Shin et al. 2015) that included an analysis of the diagnostic accuracy of sTfR testing in adults with anaemia who had serum ferritin levels of 10–100 µg/L. This single study was included in the assessment because it reported the diagnostic accuracy of sTfR and ferritin separately in a range of ferritin levels close to that specified in the PICO.

ESC noted that the reference standard used in the Shin study was a composite of three criteria, each of uncertain accuracy, and also included the index test; therefore, the study was at risk of verification and incorporation bias. Coupled with poor reporting of patient selection and uncertainty of whether a case-control design was avoided, this led to the study being assessed as being at a high risk of bias.

ESC noted the uncertainty about the sensitivity and specificity of the sTfR test compared to ferritin tests; sTfR appears to be less sensitive but perhaps more specific. Both sTfR and the sTfR/log ferritin ratio identified fewer patients with IDA (with or without ACD) than ferritin level alone, but identified more patients with ACD alone.

ESC noted that the ROC curve (Figure 7 in the assessment group critique) for sTfR/log ferritin had the highest area under the curve (AUC; 0.96). sTfR had the highest AUC of any single test (0.93) in differentiating between IDA (±ACD) and ACD alone, followed by TSAT, total iron-binding capacity, mean cell haemoglobin concentration, mean cell volume, ferritin (AUC 0.88), iron and hepcidin. The AUC for sTfR/log ferritin ratio was significantly larger than the AUC for ferritin (p=0.0086).

ESC noted that the high level of heterogeneity of the population and the complex management options for patients diagnosed with IDA and/or ACD made creating an economic model representative of these patient populations challenging and complex. Moreover, there was a paucity of clinical evidence regarding patient presentation, patient characteristics and findings on examination. ESC noted that this introduced a very high level of uncertainty regarding what additional investigations would be conducted, how often and in whom, and what changes in patient management would occur in which patients. Therefore, an economic evaluation was not conducted because of the significant uncertainties surrounding the complex diagnostic and treatment pathways with subsequent unacceptable levels of uncertainty of any cost and probability estimates.

ESC noted that the prevalence data (3.7% vs 5%, as noted above) used to estimate the costs and utilisation of the proposed items were limited and have the potential for bias.

ESC noted the price of $45 proposed by the applicant for the singular sTfR item; however, a cost of $33 was listed in the contracted assessment. Furthermore, as stated in the contracted assessment, testing can be found for as little as $16.24. ESC noted that the Department proposes that this is the price that should be reflected by the proposed item.

ESC noted that opportunity costs were not factored into the economic analysis. There is a wide range of possible additional investigations that may be undertaken in response to test results and clinical context; in the absence of sTfR testing, additional investigations and/or a trial of iron therapy may occur concurrently in response to a finding of a ferritin level of 30–100 µg/L (and TSAT <30%).

Consequently, it was uncertain that sTfR testing would make any significant impact on patient management with regards to: reducing additional investigations in those patients with

a positive test; identifying patients who will not respond to iron supplementation; allowing more timely and targeted investigations to diagnose underlying disease, by potentially earlier identification of patients who have ACD; reducing the duration of anaemia, due to changes in management informed by sTfR testing results; or impact on quality of life, due to reducing the duration of anaemia.

ESC noted that the budget implications are uncertain. An epidemiological approach was taken based on data from a single laboratory – a 1-month sample summary provided by the applicant. There was also uncertainty about the setting. Estimates were provided at the 85% rebate (primary care setting) but it is likely that some sTfR testing would be conducted in hospital (75% rebate), which was not taken into account. ESC noted that an assumption was made that all ferritin studies would be replaced by iron studies, a pre-requisite for sTfr access. ESC considered that this is not justified and hence maybe an overestimation.

ESC noted that the critique advised that services related to ACD were not included and that that the impact on both the PBS for iron, and on the hospital system, were not considered.

ESC noted that the critique identified an error in the epidemiology approach. The number of anaemic patients was multiplied by 3.7% to estimate the number eligible for sTfR testing. However, the 3.7% figure is the proportion of iron and full blood count studies that are in the eligible population, not the proportion of anaemic patients that are in the eligible population. The critique calculated that the proportion applied to the total anaemia patients should be 3.05%. The corrected values are much lower (approximately 18%) and even more discordant with the market share approach taken in the base case.

ESC noted that the estimated direct cost to the MBS in 2018 is $9.6 million rising to $11.3 million in 2021. When the additional cost of switching from ferritin quantitation to iron studies is included, the cost rises to $18.6 million in 2018 and $21.8 million in 2021. ESC noted that these estimates are based on the 85% rebate, but it is not known how many tests would be undertaken in hospital. ESC noted that the estimates are also uncertain because the clinical pathway is heterogeneous and uptake of the test is unknown.

ESC noted that most iron studies are performed for patients in the community sector and are bulk-billed, so out-of-pocket expense for patients is small. However, with more than 6 million iron studies tests per year ($200 million in 2017), the potential implications for the MBS budget of adding this test are significant.

ESC noted that there is active debate in the expert community about the use of ferritin versus iron studies.

ESC queried whether there was a lost opportunity with the analysis in the application. Limiting the population to patients having full panel iron studies missed out a group of patients who had full blood count and ferritin tests. ESC noted that the Department intended there to be two pathways and two comparators.

ESC noted that the MBS Review was concerned that more ferritin testing should be done rather than iron studies to investigate iron deficiency. ESC considered that this has good grounds because there is a $12 price difference, which is significant when there are more than 6 million tests. One option could be that the first test is always ferritin. If the result was low (e.g. 15–20 µg/L), no further testing would be required. If the ferritin level is 30–100 µg/L, then the full iron study could be done as a reflex test.

ESC suggested that MSAC could investigate potential options for the future, such as the use of ferritin tests for specific indications, or the potential to incorporate sTfR into a different pathway, as a bundle with iron studies rather than as an additional test. ESC queried whether there should be different item numbers for different populations, for ease of service provision.

15. Other significant factors

Nil

16. Applicant's comments on MSAC's Public Summary Document

The applicant is disappointed with the outcome for this application.

17. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: visit the MSAC website