



**Australian Government**  
**Department of Health**

# **Application Form**

## **(New and Amended Requests for Public Funding)**

### **(Version 0.1)**

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires in order to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

Email: [hta@health.gov.au](mailto:hta@health.gov.au)

Website: <http://www.msac.gov.au>

# Version Control

## Document History

Version Number	Date Changed	Author	Reason for Change
0.1	8 April 2016	Bianca Ledbrook	Final for Publication

## Document Approval

Version Number	Date Changed	Author	Reason for Change
1.0	8 April 2016	Bianca Ledbrook	Document released for publication

## PART 1 – APPLICANT DETAILS

**1. Applicant details (primary and alternative contacts)**

Corporation / partnership details <i>(where relevant):</i> Corporation name: ABN: Business trading name:	The Royal College of Pathologists of Australasia <b>Redacted</b> <b>Redacted</b>
Primary contact name:	<b>Redacted</b>
Primary contact numbers: Business: Mobile: Email:	<b>Redacted</b> <b>Redacted</b> <b>Redacted</b>
Alternative contact name:	<b>Redacted</b>
Alternative contact numbers: Business: Mobile: Email:	<b>Redacted</b> <b>Redacted</b> <b>Redacted</b>

**2. (a) Are you a lobbyist acting on behalf of an Applicant?**

Yes:

No:

**(b) If yes, are you listed on the Register of Lobbyists?**

Yes:

No:

## PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

### 3. Application title

Serum soluble transferrin receptor

### 4. Provide a succinct description of the medical condition relevant to the proposed service (*no more than 150 words – further information will be requested in Part 6 of the Application Form*)

The proposed service is now an established test for the investigation of anaemia, a major public health problem globally affecting approx. a third of the world's population. Anaemia is also common in Australia<sup>a</sup> and it is estimated that fifty per cent of anaemia cases are due to iron deficiency anaemia (IDA) with women of child bearing age, pregnant women and young children at highest risk.<sup>b</sup> Distinguishing between IDA and anaemia of chronic disease (ACD)<sup>c</sup> can be difficult<sup>d</sup> using tests currently available in Australia with public funding through the Medical Benefit Schedule (MBS). The proposed service is applicable to other anaemic conditions such as microcytic anaemia where ferritin levels are often normal and functional anaemia where tissue iron deficiency is present despite adequate iron stores.<sup>e</sup>

- a. Khambalia AZ, Collins CE, Roberts CL, et al: Iron deficiency in early pregnancy using serum ferritin and soluble transferrin receptor concentrations are associated with pregnancy and birth outcomes. Eur J Clin Nutr 70:358-63, 2016.
- b. Lopez A, Cacoub P, Macdougall IC, et al: Iron deficiency anaemia. Lancet 387:907-16, 2016
- c. Fitzsimons EJ, Brock JH: The anaemia of chronic disease. BMJ 322:811-2, 2001
- d. Baillie FJ, Morrison AE, Fergus I: Soluble transferrin receptor: a discriminating assay for iron deficiency. Clin Lab Haematol 25:353-7, 2003
- e. Beguin Y: Soluble transferrin receptor for the evaluation of erythropoiesis and iron status. Clin Chim Acta 329:9-22, 2003

### 5. Provide a succinct description of the proposed medical service (*no more than 150 words – further information will be requested in Part 6 of the Application Form*)

Serum soluble transferrin receptor (sTfR) is a sensitive, early, quantitative marker of iron depletion in the diagnosis of iron deficiency anaemia (IDA) and anaemia of chronic disease (ACD). The introduction of iron into cells is mediated by interaction with a specific membrane receptor, the transferrin receptor (TfR with transferrin the iron transport protein. The soluble form of TfR found in serum is a truncated monomer of the tissue receptor, circulating as a complex of transferrin and its receptor.<sup>c</sup> Measurement of sTfR allows evaluation of the absolute rate of erythropoiesis and bone marrow proliferation capacity particularly when serum ferritin levels are normal or greater than normal.

### 6. (a) Is this a request for MBS funding?

Yes:

No:

### (b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

Amendment to existing MBS item(s):

New MBS item(s):

### (c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:

--

**(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?**

- i. An amendment to the way the service is clinically delivered under the existing item(s)
- ii. An amendment to the patient population under the existing item(s)
- iii. An amendment to the schedule fee of the existing item(s)
- iv. An amendment to the time and complexity of an existing item(s)
- v. Access to an existing item(s) by a different health practitioner group
- vi. Minor amendments to the item descriptor that does not affect how the service is delivered
- vii. An amendment to an existing specific single consultation item
- viii. An amendment to an existing global consultation item(s)
- ix. Other (please describe below)


--

**(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?**

- i. A new item which also seeks to allow access to the MBS for a specific health practitioner group
- ii. A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
- iii. A new item for a specific single consultation item
- iv. A new item for a global consultation item(s)

x

**(f) Is the proposed service seeking public funding other than the MBS?**

Yes:   
No:

**(g) If yes, please advise:**

--

**7. What is the type of service:**

- Therapeutic medical service
- Investigative medical service
- Single consultation medical service
- Global consultation medical service
- Allied health service
- Co-dependent technology
- Hybrid health technology

x

**8. For investigative services, advise the specific purpose of performing the service (which could be one or more of the following):**

- i. To be used as a screening tool in asymptomatic populations

--

- i. To be used as a screening tool in asymptomatic populations
- ii. Assists in establishing a diagnosis in symptomatic patients
- iii. Provides information about prognosis
- iv. Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
- v. Monitors a patient over time to assess treatment response and guide subsequent treatment decisions

X
X
X
X

**9. Does your service rely on another medical product to achieve or to enhance its intended effect?**

Pharmaceutical / Biological	<input type="checkbox"/>
Prosthesis or device	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>

**10. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?**

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

**(b) If yes, please list the relevant PBS item code(s)?**

**(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?**

Yes (please provide PBAC submission item number below)	<input type="checkbox"/>
No	<input type="checkbox"/>

**(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?**

Trade name	<input type="text"/>
Generic name	<input type="text"/>

**11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?**

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

**(b) If yes, please provide the following information (where relevant):**

Billing code(s)	<input type="text"/>
Trade name of prostheses	<input type="text"/>
Clinical name of prostheses	<input type="text"/>

Billing code(s)  
Other device components  
delivered as part of the service


**(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?**

Yes   
No

**(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?**

Yes   
No

**(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s).**

--

**12. Please identify any single and / or multi-use consumables delivered as part of the service?**

Single use consumables

Several assays are available for serum soluble transferrin receptor and all require single use consumables such as laboratory pipette tips.

This application does not endorse any one specific commercial product. The IVD will be subject to TGA processes and laboratory validation. A detailed listing of all products and their consumables is beyond the scope of this application. It should be noted that new products will continue to be developed using the same scientific principles.

Multi-use consumables

--

## PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

13. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:

Type of therapeutic good	In-vitro diagnostic test
Manufacturer's name	Various
Sponsor's name	Not applicable

(b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

Class III	x
AIMD	
N/A	

14. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

Yes		If yes, please provide supporting documentation as an attachment to this application form
No	x	

(b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

Yes (please provide details below)	x
No	

ARTG listing, registration or inclusion number:	178153
TGA approved indication(s), if applicable:	
TGA approved purpose(s), if applicable:	

15. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

Yes (please provide details below)	
No	

Date of submission to TGA	
Estimated date by which TGA approval can be expected	
TGA Application ID	
TGA approved indication(s), if applicable	
TGA approved purpose(s), if applicable	

**16. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?**

Yes (please provide details below)


No

Estimated date of submission to TGA

Proposed indication(s), if applicable

Proposed purpose(s), if applicable


## PART 4 – SUMMARY OF EVIDENCE

17. Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only). *Please do not attach full text articles, this is just intended to be a summary.*

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
1.	Study of diagnostic accuracy	Beguin Y: Soluble transferrin receptor for the evaluation of erythropoiesis and iron status. Clin Chim Acta 329:9-22, 2003	Study of the utility of soluble transferrin receptor (sTfR) to investigate anaemia when changes in haemoglobin and iron status are not apparent; in microcytic anemia, concomitant iron deficiency in patients with inflammation and patients with malignancies. The study concluded that sTfR represents a valuable quantitative assay of marrow erythropoietic activity and as a marker of tissue iron deficiency.	<a href="http://www.sciencedirect.com/science/article/pii/S009898103000056">http://www.sciencedirect.com/science/article/pii/S009898103000056</a>	2003
2.	Study of diagnostic accuracy	Berlin T, Meyer A, Rotman-Pikielny P, et al: Soluble transferrin receptor as a diagnostic laboratory test for detection of iron deficiency anemia in acute illness of hospitalized patients. Isr Med Assoc J 13:96-8, 2011	A study of sTfR as a marker for further gastrointestinal tract (GIT) investigation in cases of anemia where the level of ferritin was normal or increased. 32 patients with anemia, high sTfR levels (> 5.0 mg/L) and normal or high ferritin were included. 22 (68%) were found to have underlying causes of iron deficiency anaemia (IDA) (such as polyps, carcinoma, ulcer or inflammation). The study concluded that high sTfR may be a good indicator of IDA caused by GIT bleeding when the ferritin level is normal or high.	<a href="http://www.ima.org.il/IMA/J/ViewArticle.aspx?year=2011&amp;month=02&amp;page=96">http://www.ima.org.il/IMA/J/ViewArticle.aspx?year=2011&amp;month=02&amp;page=96</a>	2011
3.	Study of diagnostic accuracy	Baillie FJ, Morrison AE, Fergus I: Soluble transferrin receptor: a discriminating assay for iron deficiency. Clin Lab Haematol 25:353-7, 2003	A study of IDA investigations comparing sTfR concentrations with the gold standard of iron stores; bone marrow iron. The sTfR concentration was shown to be the most efficient test in predicting bone marrow iron stores in 20 patients with anaemia of chronic disease (ACD) with 75% efficiency and in 18 patients with rheumatoid arthritis (RA) 94% efficiency. The study concluded that sTfR may be a useful addition in the differential diagnosis of ACD and IDA.	<a href="http://onlinelibrary.wiley.com/doi/10.1046/j.0141-9854.2003.00548.x/abstract">http://onlinelibrary.wiley.com/doi/10.1046/j.0141-9854.2003.00548.x/abstract</a>	2003

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
4.	Study of diagnostic accuracy	Khambalia AZ, Collins CE, Roberts CL, et al: Iron deficiency in early pregnancy using serum ferritin and soluble transferrin receptor concentrations are associated with pregnancy and birth outcomes. Eur J Clin Nutr 70:358-63, 2016.	Australian study of archived serum samples of 4420 women attending first trimester screening with birth and hospital data to ascertain maternal characteristics and pregnancy outcomes. Sera were analysed for iron stores (ferritin), lack of iron in the tissues (sTfR); and inflammatory (C-reactive protein (CRP)) biomarkers. Total body iron (TBI) was calculated from serum ferritin (SF) and sTfR concentrations. The study demonstrated the utility of sTfR along with other markers of IDA to conclude that nearly one in five Australian women begins pregnancy with IDA.	<a href="http://www.nature.com/ejcn/journal/v70/n3/full/ejcn2015157a.html">http://www.nature.com/ejcn/journal/v70/n3/full/ejcn2015157a.html</a>	2016
5.	Study of diagnostic accuracy	Shin DH, Kim HS, Park MJ, et al: Utility of Access Soluble Transferrin Receptor (sTfR) and sTfR/log Ferritin Index in Diagnosing Iron Deficiency Anemia. Ann Clin Lab Sci 45:396-402, 2015	Study of the utility of sTfR and other markers of serum iron (complete blood cell count, serum iron, total iron-binding capacity (TIBC), C-reactive protein (CRP), ferritin, and hepcidin) in 367 patients with anaemia (IDA 157, ACD 210 and 80 normal controls). The study concluded that while the most accurate diagnostic test to differentiate IDA from ACD was SF, sTfR assay outperformed other tests in the ferritin grey zone and the sTfR/log ferritin index was the most reliable parameter in both scenarios.	<a href="http://www.annclinlabsci.org/content/45/4/396.long">http://www.annclinlabsci.org/content/45/4/396.long</a>	2015
6.					
7.					
8.					
9.					
10.					
11.					
12.					
13.					
14.					
15.					

*\* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.*

*\*\*Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes.*

*\*\*\* If the publication is a follow-up to an initial publication, please advise.*

18. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). *Please do not attach full text articles, this is just intended to be a summary.*

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date* **
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					
13.					
14.					
15.					

\* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

\*\*Provide high level information including population numbers and whether patients are being recruited or in post-recruitment.

\*\*\*Date of when results will be made available (to the best of your knowledge).

## PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

19. List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a letter of support for each group nominated).

Royal College of Pathologists of Australasia

20. List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service).

It should be noted that the RCPA provides the comparator services so no others would be impacted by the medical service.

21. List the relevant consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated).

Not applicable

22. List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service.

Not applicable

23. Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):

Name of expert 1	Redacted
Telephone number(s)	Redacted
Email address	Redacted
Justification of expertise	Redacted
Name of expert 2	Redacted
Telephone number(s)	Redacted
Email address	Redacted
Justification of expertise	Redacted

*Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.*

## PART 6 – POPULATION (AND PRIOR TESTS), INDICATION, COMPARATOR, OUTCOME (PICO)

### ***PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION***

- 24. Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease in terms of both morbidity and mortality.**

Anaemia is a major public health problem globally affecting approx. a third of the world's population. As iron is needed for efficient oxygen transport in the body, the morbidity of anaemia is well recognised in relation to basic physical functions. Fatigue, shortness of breath, dizziness, difficulty concentrating and physical weakness affect a patient's ability to carry out everyday tasks.

Anaemia impacts on rates of morbidity and mortality particularly in mothers and children.<sup>a</sup> Elderly patients with anaemia are also more likely to be hospitalised and have a higher risk of dying than those without the condition.<sup>b</sup>

- a. Lopez A, Cacoub P, Macdougall IC, et al: Iron deficiency anaemia. Lancet 387:907-16, 2016
- b. Vogin GD: Late-Life Anemia Affects Morbidity and Mortality, Medscape, 2003 available at <http://www.medscape.com/viewarticle/466114>

- 25. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service.**

Patients presenting to a medical practitioner with symptoms of anaemia would be referred for pathology testing with a full blood count (FBC) and in some cases, erythrocyte sedimentation rate (ESR), C-reactive protein (CRP) ferritin and related iron studies. In situations where the patient's haemoglobin is low and CRP is elevated but serum ferritin (Se Fe) is normal (or greater than normal), the underlying cause of the anaemia is difficult to diagnose using current testing.

- 26. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point).**

Patients presenting to a medical practitioner with symptoms of anaemia would be referred for pathology testing with a FBC, ferritin, and possibly ESR, CRP and iron studies. Where the patient's haemoglobin is low but serum ferritin is normal (or greater than normal), the test would assist in determining the cause of anaemia.

The proposed medical service Serum soluble transferrin receptor would assist in distinguishing IDA from ACD.

**PART 6b – INFORMATION ABOUT THE INTERVENTION**

**27. Describe the key components and clinical steps involved in delivering the proposed medical service.**

Serum soluble transferrin receptor testing requires a venepuncture to be performed on the patient for the collection of a blood sample that is referred to a pathology laboratory for biochemical analysis.

**28. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?**

Various assays are available for sTfR using the same scientific principles and no single commercial or trademark product is endorsed in this application.

**29. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?**

Not applicable

**30. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency).**

The medical service would be limited to patients with anaemia.

**31. If applicable, identify any healthcare resources or other medical services that would need to be delivered at the same time as the proposed medical service.**

Not applicable

**32. If applicable, advise which health professionals will primarily deliver the proposed service.**

Testing would be provided by Approved Pathology Practitioners in line with other tests in the MBS Pathology Table.

**33. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery.**

Not applicable

**34. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it.**

Testing would be delivered only by Approved Pathology Practitioners in Accredited Pathology Laboratories (as defined in MBS Pathology table) by referral only by registered Medical Practitioners (non-pathologists) in line with other tests in the MBS Pathology Table.

**35. If applicable, advise what type of training or qualifications would be required to perform the proposed service as well as any accreditation requirements to support service delivery.**

Testing would be delivered only by Approved Pathology Practitioners in Accredited Pathology Laboratories (as defined in MBS Pathology table).

**36. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select all relevant settings)**

Inpatient private hospital	<input type="checkbox"/>
Inpatient public hospital	<input type="checkbox"/>
Outpatient clinic	<input type="checkbox"/>
Emergency Department	<input type="checkbox"/>
Consulting rooms	<input type="checkbox"/>
Day surgery centre	<input type="checkbox"/>
Residential aged care facility	<input type="checkbox"/>
Patient's home	<input type="checkbox"/>
Laboratory	<input checked="" type="checkbox"/>
Other – please specify	<input type="checkbox"/>

**(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each.**

37. Is the proposed medical service intended to be entirely rendered in Australia?

Yes

x

No (please specify below)

--

**PART 6c – INFORMATION ABOUT THE COMPARATOR(S)**

38. Nominate the appropriate comparator(s) for the proposed medical service, i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system (including identifying health care resources that are needed to be delivered at the same time as the comparator service).

The comparator is investigation of anaemia without soluble transferrin receptor testing
---

39. Does the medical service that has been nominated as the comparator have an existing MBS item number(s)?

Yes (please provide all relevant MBS numbers below)

X

No

--

40. Define and summarise the current clinical management pathways that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards including health care resources).

The clinical management pathway after the comparator (no testing) would include the usual treatments for anaemia such as oral iron supplements. However, where IDA is not distinguished from ACD, the patient's anaemia may not improve. Anaemia may need to be treated with iron infusion to overcome the factors preventing uptake of oral iron. ACD may require investigation with appropriate testing for the suspected underlying condition such as gastroscopy, colonoscopy, bone marrow trephine, radiological cancer scans and immunological testing and does not respond to iron replacement.
--

41. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?

Yes

x

No

(b) If yes, please outline the extent of which the current service/comparator is expected to be substituted.

The comparator is investigation without the test.
---

**42. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service including variation in health care resources (Refer to Question 39 as baseline).**

Currently patients with anaemia with but normal or greater than normal serum ferritin are managed in a variety of ways depending on the level of understanding of the treating clinician. A long process of trial and error that seeks to improve the patient’s haemoglobin.

Serum soluble transferrin receptor would reduce the time required to distinguish ICD from ACD and reduce unnecessary investigations with such as gastroscopy, colonoscopy, bone marrow biopsy, radiological cancer scans and immunological testing.

**PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME**

**43. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms).**

Serum soluble transferrin receptor is superior clinically when compared to current publicly funded investigations of anaemia in distinguishing difficult to diagnosis iron deficiency anaemia and anaemia of chronic disease.

The comparative benefits are in distinguishing the root causes of the anaemia and providing the most appropriate treatment. It provides an earlier diagnosis of anaemia that will not respond to iron supplementation. Diagnosis of ACD allows for earlier and more targeted invasive procedures to diagnose underlying disease.

sTfR provides best pathology testing to determine the diagnosis, prognosis and for the appropriate selection of treatment where a patient has anaemia in the presence of normal (or greater than normal) serum ferritin.

**44. Please advise if the overall clinical claim is for:**

Superiority	x
Non-inferiority	

**45. List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:**

<b>Safety Outcomes</b>
sTfR is equivalent in safety to other pathology tests involving venepuncture for blood sampling.
Reduction of morbidity and mortality.
Reduced invasive investigations.

<b>Safety Outcomes</b>
<b>Clinical Effectiveness Outcomes</b>
sTfR is superior in distinguishing ICD from ACD.
The cause of anaemia is diagnosed earlier reducing the duration of anaemia.
Patients receive more appropriate treatment of their condition.
Fewer invasive procedures are required reducing the risk of adverse events.
sTfR is best practice to determine diagnosis, prognosis and for the appropriate selection of treatment for anaemia where serum ferritin is normal (or greater than normal).

## PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

**46. Estimate the prevalence and/or incidence of the proposed population.**

1,600,000

Estimated as 30% of patients currently tested with iron studies; 5,400,000\*.

*\*Source: Medicare statistics for MBS item 66596 iron studies Jul 2015 to Jun 2016. Percentage estimated as 30% who may require sFtR, taken from laboratory internal data on patients with low Hb and normal or greater than normal Se Fe.*

**47. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year.**

One- two times per year

Some patients may require ongoing monitoring but sTR may not be required for monitoring. Therefore two per year is a reasonable average estimate.

**48. How many years would the proposed medical service(s) be required for the patient?**

One year

Some patients with chronic disease may require further use of the test to determine whether iron deficiency is contribution to the ongoing chronic condition.

**49. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year.**

3,200,000 (twice per year)

**50. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service.**

Uptake in the next three years will result in all of the at risk population using the test in diagnosis. Testing is likely to increase at approx. 10% per year (similar to MBS item 66596 iron studies).

Leakage to populations not targeted by the service would be restricted by the item descriptor.

## PART 8 – COST INFORMATION

51. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown.

Serum soluble transferrin receptor is likely to cost \$45 to perform.	
<b>Equipment and resources</b>	<b>Per test</b>
IVD, ancillary reagents	10.00
Labour medical (consultant pathologist)	3.00
Labour scientific	10.00
Labour on costs	5.00
Depreciation, overheads, admin and IT	5.00
<b>Total</b>	<b>\$33.00</b>

52. Specify how long the proposed medical service typically takes to perform.

On arrival in lab, 24 hours
-----------------------------

53. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

Category (proposed category number) – (proposed category description)
<p>Proposed item descriptor</p> <p>Quantitation in serum of soluble transferrin receptor in patients with anaemia and normal or greater than normal serum ferritin.</p> <p>Fee: \$33</p>

## PART 9 – FEEDBACK

The Department is interested in your feedback.

### 54. How long did it take to complete the Application Form?

Seven days

### 55. (a) Was the Application Form clear and easy to complete?

Yes	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>

### (b) If no, provide areas of concern.

Mostly clear and easy to complete but some information on IVDs, clinical management flow charts and others are quite difficult.

### 56. (a) Are the associated Guidelines to the Application Form useful?

Yes	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>

### (b) If no, what areas did you find not to be useful?

The guidelines do not provide any extra information compared with the form. The guidelines would benefit by including an explanation of the application process and schedule.

### 57. (a) Is there any information that the Department should consider in the future relating to the questions within the Application Form that is not contained in the Application Form?

Yes	<input checked="" type="checkbox"/>
No	<input type="checkbox"/>

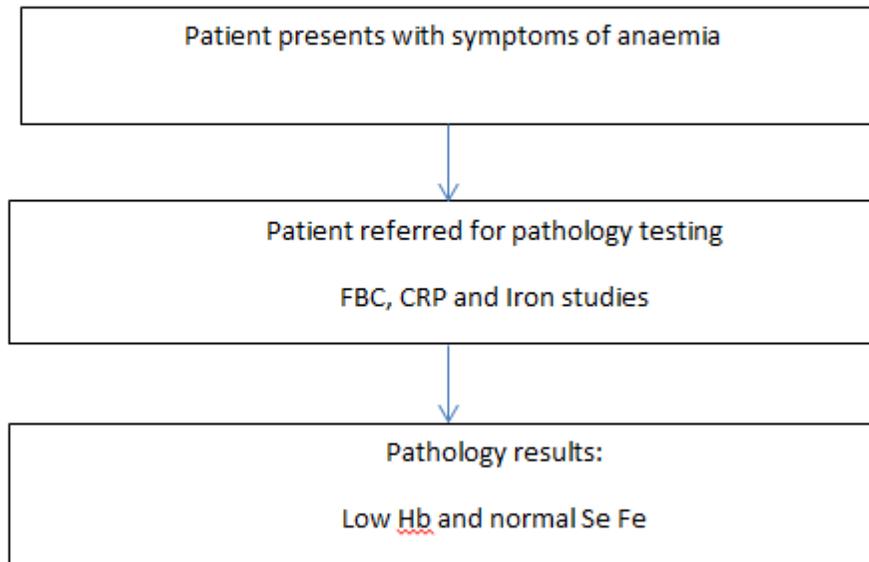
### (b) If yes, please advise:

The form could be better tailored for Pathology items that are not technology-specific (i.e. not a single TGA product) and already have established rules in the MBS (Approved Pathology Practitioners; accredited laboratories; referrals by registered medical practitioners).

**Flowcharts**

**Q26 Current clinical pathway before patient is eligible for proposed medical service**

**Serum soluble transferrin receptor**



**Q40 Current clinical pathway after comparator  
(no testing)**

