



Australian Government

Department of Health

Application Form

(New and Amended

Requests for Public Funding)

(Version 2.4)

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.

Phone: +61 2 6289 7550

Fax: +61 2 6289 5540

Email: hta@health.gov.au

Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant):

Corporation name: The Royal College of Pathologists of Australasia (RCPA)

ABN: Redacted

Business trading name: Redacted

Primary contact name: Redacted

Primary contact numbers

Business: Redacted

Mobile: Redacted

Email: Redacted

Alternative contact name: Redacted

Alternative contact numbers

Business: Redacted

Mobile: Redacted

Email: Redacted

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

Somatic tumour gene testing for the diagnosis of Diffuse Large B Cell Lymphoma, Multiple Myeloma and Non-Hodgkin Lymphoma Subtypes

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

Diffuse large B cell lymphoma; copy number aberrations and / or mutations for the diagnosis and classification of plasma cell myeloma; and rare sub-types of non-hodgkin lymphoma that respond poorly to conventional chemotherapy.

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

The characterisation of: rearrangements in BCL2, BC16, MYC genes for detection of cases of 'double-hit' diffuse large B cell lymphoma, which require more intensive chemotherapy in view of the more aggressive nature of the lymphoma; copy number changes or mutations for the diagnosis and classification of neoplasms or the detection of minimal residual disease of patients with plasma cell myeloma; and histological diagnosis and classification for rare subtypes of non-hodgkin lymphoma.

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:

Not applicable

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

Not applicable

- 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):

Insert description of 'other' amendment here

(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)

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

Yes

No

(g) If yes, please advise:

Not applicable

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

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
- 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

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

- Pharmaceutical / Biological
- Prosthesis or device
- No

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

Not applicable

- Yes
- No

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

Not applicable

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

Not applicable

- Yes (please provide PBAC submission item number below)
- No

Insert PBAC submission item number here

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

Not applicable

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

Not applicable

- Yes
- No

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

Not applicable

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

Not applicable

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?

Not applicable

Yes

No

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

Not applicable

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

Single use consumables:

Diffuse Large B Cell Lymphoma

A number different assays that all require the use of consumables can be used to detect the genetic changes described above including fluorescent in situ hybridisation (FISH), polymerase chain reaction (PCR), Sanger sequencing, and next generation sequencing (NGS). FISH is the most commonly employed assay.

Multiple Myeloma

Non-Hodgkin Lymphoma

A wide number of assays and techniques can be used to detect the genetic changes described above including polymerase chain reaction (PCR), Sanger sequencing, next generation sequencing (NGS) and fluorescent in situ hybridisation (FISH).

An exhaustive listing is beyond the scope of this application given the multiple assays/ techniques that can be used. These will continue to evolve as new diagnostic changes are reported across tumour types.

Further information can be provided if required.

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
 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

- (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 (if yes, please provide details below)
 No

ARTG listing, registration or inclusion number:

ARTG licence numbers for Acquired genetic alteration IVDs including but not limited to:

AA-Med Pty Ltd 214482
Abacus ALS Pty Ltd 255352 256572 262298
Abbott Australasia Pty Ltd Molecular Division 196286
Biomerieux Australia Pty Ltd 217781
Bio-Strategy Pty Ltd 226487
Carl Zeiss Pty Ltd 266568
Cepheid Holdings Pty Ltd 226631
Dako Australia Pty Ltd 199420 264573
In Vitro Technologies Pty Ltd 225995
Key Diagnostics Pty Ltd 270292
Leica Microsystems Pty Ltd 191254
Qiagen Pty Ltd 214994 226453 238792
Roche Diagnostics Australia Pty Limited 180933
192394 192395 194319 196363 Thermo Fisher
Scientific Australia Pty Ltd 227503 256113
Vela Diagnostics Australia Pty Ltd 228024 235394

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?

Not applicable

- Yes (please provide details below)
 No

Date of submission to TGA: Insert date of submission here

Estimated date by which TGA approval can be expected: Insert estimated date here

TGA Application ID: Insert TGA Application ID here

TGA approved indication(s), if applicable: If applicable, insert description of TGA approved indication(s) here

TGA approved purpose(s), if applicable: If applicable, insert description of TGA approved purpose(s) here

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?

Not applicable

Yes (please provide details below)

No

Estimated date of submission to TGA: Insert date of submission here

Proposed indication(s), if applicable: If applicable, insert description of proposed indication(s)

Proposed purpose(s), if applicable: If applicable, insert description of proposed purpose(s) here

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.*

Diffuse Large B Cell Lymphoma

	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.	Clinical practice guidelines	Australian Cancer Network Diagnosis and Management of Lymphoma Guidelines Working Party: Clinical Practice Guidelines or the Diagnosis and Management of Lymphoma. The Cancer Council Australia and Australian Cancer Network. Sydney 2005	NHMRC clinical practice guidelines providing levels of evidence for the recommendations.	Clinical Practice Guidelines for the Diagnosis and Management of Lymphoma	8 Dec 2005
2.	Clinical practice guidelines	Swerdlow SC, E. Lee Harris, N. Jaffe, E.S. Pileri, S.A. Stein, H. Thiele, J. Vardiman, J.W.: WHO Classification of Tumours of Haematopoietic and Lymphoid Tissue. Lyon, France, IARC Press, 2008	World Health Organization clinical practice guidelines on the classification of tumours providing levels of evidence for the recommendations.	Book –no URL available	2008
3.	Clinical practice guidelines	Parker A, Bain B, Devereux S, et al: British Committee for Standards in Haematology. Best Practice in Lymphoma Diagnosis and Reporting. Royal College of Pathologists, London, 2010	UK clinical practice guidelines on the classification of haematological malignancies providing levels of evidence for the recommendations.	Best Practice in Lymphoma Diagnosis and Reporting	2010
4.	Educational publication	Sarkozy C, Traverse-Glehen A, Coiffier B. Double-hit and double-protein-expression lymphomas: aggressive and refractory lymphomas. Lancet Oncol.	Review of clinical implications of gene rearrangements in double hit lymphomas.	Double-hit and double-protein-expression lymphomas: aggressive and refractory lymphomas	2015
5.	Clinical trial	Horn H, Ziepert M, Becher C, et al. MYC	Results from the RICOVER clinical	MYC status in concert with BCL2	2013

	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***
		status in concert with BCL2 and BCL6 expression predicts outcome in diffuse large B-cell lymphoma. Blood. 2013;121(12):2253-63.	trial demonstrating poorer outcomes for DLBCL with MYC, BCL2 and BCL6 rearrangements following treatment with R-CHOP	and BCL6 expression predicts outcome in diffuse large B-cell lymphoma	
6.	Observational study	Agarwal R, Lade S, Liew D, et al. Role of immunohistochemistry in the era of genetic testing in MYC-positive aggressive B-cell lymphomas: a study of 209 cases. J Clin Pathol. 2015	Victorian study of the utility of immunohistochemistry for MYC-positive B-cell lymphomas	Role of immunohistochemistry in the era of genetic testing in MYC-positive aggressive B-cell lymphomas: a study of 209 cases	2017

Multiple Myeloma

	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.	Clinical practice guidelines	Swerdlow SC, E. Lee Harris, N. Jaffe, E.S. Pileri, S.A. Stein, H. Thiele, J. Vardiman, J.W.: WHO Classification of Tumours of Haematopoietic and Lymphoid Tissue. Lyon, France, IARC Press, 2008	World Health Organization clinical practice guidelines on the classification of tumours providing levels of evidence for the recommendations	Book –no URL available	2008
2.	Clinical practice guidelines	Quach H, Joshua D, et al: Treatment of patients with multiple myeloma who are eligible for stem cell transplantation: position statement of the Myeloma Foundation of Australia Medical and Scientific Advisory Group.	Position statement of the Myeloma Foundation of Australia Medical and Scientific Advisory Group providing levels of evidence for recommendations	Treatment of patients with multiple myeloma who are not eligible for stem cell transplantation: position statement of the myeloma foundation of Australia Medical and Scientific	2015

	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***
		Intern Med J 45(1):94-105, 2015		Advisory Group	
3.	Literature review	Paiva B, van Dongen JJM, Orfao A: New criteria for response assessment: role of minimal residual disease in multiple myeloma. Blood 125:3059-3068, 2015	Summary of data indicating that minimal residual disease information can be used as biomarker to evaluate the efficacy of different treatment strategies, help on treatment decisions, and act as surrogate predictor for overall survival.	New criteria for response assessment: role of minimal residual disease in multiple myeloma	14 May 2005
4.	Observational study	Rare Cancers Australia: Just a Little More Time Rare Cancers Update Report. 2016	A review of available cancer data investigating the disparities existing for incidence, mortality and survival across the cancer spectrum. The study provided a definition for rare cancers, and the burden of disease that rare and less common cancers pose across all ages in Australia	Just a Little More Time – Rare Cancers Baseline Report.	2016
5.	Health economics study	Sabatini LM, Mathews C, Ptak D, et al: Genomic Sequencing Procedure Microcosting Analysis and Health Economic Cost-Impact Analysis: A Report of the Association for Molecular Pathology. J of Mol Diagn 18:319-328,	US Study by Association for Molecular Pathology on cost and value analysis of specific genomic sequencing procedures (GSPs) gathered from representative laboratories' data. Cost-impact models for three clinical scenarios were generated - advanced non-small-cell lung cancer sensorineural hearing loss, and paediatric neurodevelopmental disorders of unknown genetic aetiology.	Genomic Sequencing Procedure Microcosting Analysis and Health Economic Cost-Impact Analysis: A Report of the Association for Molecular Pathology	2014

Non-Hodgkin Lymphoma

	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.	Clinical practice guidelines	Australian Cancer Network Diagnosis and Management of Lymphoma Guidelines Working Party: Clinical Practice Guidelines or the Diagnosis and Management of Lymphoma. The Cancer Council Australia and Australian Cancer Network. Sydney 2005	NHMRC clinical practice guidelines providing levels of evidence for the recommendations	Clinical Practice Guidelines or the Diagnosis and Management of Lymphoma	8 Dec 2005
2.	Clinical practice guidelines	Swerdlow SC, E. Lee Harris, N. Jaffe, E.S. Pileri, S.A. Stein, H. Thiele, J. Vardiman, J.W.: WHO Classification of Tumours of Haematopoietic and Lymphoid Tissue. Lyon, France, IARC Press, 2008	World Health Organization clinical practice guidelines on the classification of tumours providing levels of evidence for the recommendations	Book –no URL available	2008
3.	Clinical practice guidelines	Parker A, Bain B, Devereux S, et al: British Committee for Standards in Haematology. Best Practice in Lymphoma Diagnosis and Reporting. Royal College of Pathologists. London, 2010	UK clinical practice guidelines on the classification of haematological malignancies providing levels of evidence for the recommendations	Best Practice in Lymphoma Diagnosis and Reporting	2010
4.	Observational study	Bouska A, Bi C, Lone W, et al. Adult high-grade B-cell lymphoma with Burkitt lymphoma signature: genomic	Study of the molecular features of Burkitt lymphoma demonstrating the MYC-ARF-p53 axis as the primary	Adult high-grade B-cell lymphoma with Burkitt lymphoma signature: genomic features	

	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***
		features and potential therapeutic targets. Blood. 2017;130(16):1819-31.	deregulated pathway.	and potential therapeutic targets	
5.	Educational publication	Sud A, Dearden C. T-cell Prolymphocytic Leukemia. Hematol Oncol Clin North Am. 2017;31(2):273-83.	Diagnostic criteria of T-cell prolymphocytic leukemia including clinical features, morphology, immunophenotyping, cytogenetics, and molecular features.	T-cell Prolymphocytic Leukemia.	
6.	Observational study	Jain P, Aoki E, Keating M, et al. Characteristics, outcomes, prognostic factors and treatment of patients with T-cell prolymphocytic leukemia (T-PLL). Ann Oncol. 2017;28(7):1554-9.	Observational study of 119 patients with T-cell prolymphocytic leukemia.	Characteristics, outcomes, prognostic factors and treatment of patients with T-cell prolymphocytic leukemia (T-PLL).	2008
7.	Observational study	Zeng Y, Feldman AL. Genetics of Anaplastic Large Cell Lymphoma. Leukemia & lymphoma. 2016;57(1):21-7.	Report on recent clinical, pathologic, and genetic data on the heterogeneity ALK-negative ALCLs.	Genetics of Anaplastic Large Cell Lymphoma	2016
8.	Observational study	Seto M. Cyclin D1-negative mantle cell lymphoma. Blood. 2013;121(8):1249.	Report on prevalence of Cyclin D1- (CCND1) negative SOX11-positive mantle cell lymphoma (MCL) with CCND2 gene rearrangements predictive for disease prognosis and indicative of the need for intensive therapy.	Cyclin D1-negative mantle cell lymphoma	2013

	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***
9.	Clinical review	Weidmann E. Hepatosplenic T cell lymphoma. A review on 45 cases since the first report describing the disease as a distinct lymphoma entity in 1990. Leukemia. 2000;14(6):991-7.	Review of clinicopathological, immunophenotypical, molecular biological, cytogenetical and biological findings, and diagnostic and therapeutic difficulties in hepatosplenic gammadelta T cell lymphoma.	Hepatosplenic T cell lymphoma. A review on 45 cases since the first report describing the disease as a distinct lymphoma entity in 1990	2000
4.	Health economics study	Sabatini LM, Mathews C, Ptak D, et al: Genomic Sequencing Procedure Microcosting Analysis and Health Economic Cost-Impact Analysis: A Report of the Association for Molecular Pathology. J of Mol Diagn 18:319-328,	US Study by Association for Molecular Pathology on cost and value analysis of specific genomic sequencing procedures (GSPs) gathered from representative laboratories' data. Cost-impact models for three clinical scenarios were generated - advanced non-small-cell lung cancer sensorineural hearing loss, and paediatric neurodevelopmental disorders of unknown genetic aetiology.	Genomic Sequencing Procedure Microcosting Analysis and Health Economic Cost-Impact Analysis: A Report of the Association for Molecular Pathology	2014
10.	Observational study	Rare Cancers Australia: Just a Little More Time Rare Cancers Update Report. 2016	A review of available cancer data investigating the disparities existing for incidence, mortality and survival across the cancer spectrum. The study provided a definition for rare cancers, and the burden of disease that rare and less common cancers pose across all ages in Australia	Just a Little More Time – Rare Cancers Baseline Report.	2016

- 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.	For yet to be published research that may have results relevant to your application, insert the type of study design in this column and columns below	For yet to be published research that may have results relevant to your application, insert the title of research (including any trial identifier if relevant) in this column and columns below	For yet to be published research that may have results relevant to your application, insert a short description of research (max 50 words) in this column and columns below	For yet to be published research that may have results relevant to your application, insert a website link to this research (if available) in this column and columns below	For yet to be published research that may have results relevant to your application, insert date in this column and columns below
2.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
3.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
4.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
5.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
6.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
7.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
8.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
9.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date

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 statement of clinical relevance from each group nominated):

The Royal College of Pathologists of Australasia
Pathology Australia
The Royal Australasian College of Physicians
The Royal Australasian College of Surgeons
Clinical Oncology Society of Australia (COSA)
Human Genetics Society of Australia
Clinical Oncology Society of Australia (COSA)
Rare Cancer Group

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

The RCPA provides the comparator service. Other relevant professional bodies are:
The Royal Australasian College of Physicians
The Royal Australasian College of Surgeons
Clinical Oncology Society of Australia (COSA)

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

Cancer Voices
Rare Cancers Australia
Leukaemia Foundation
Without a Ribbon
Unicorn Foundation

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:**

Diffuse Large B Cell Lymphoma

Specific gene rearrangements, mutations and/or copy number changes are seen in a range of neoplasms and detection of these changes in Diffuse Large B Cell Lymphoma (LBCL) has become best practice to determine definitive diagnosis/classification, prognosis and for the appropriate selection of treatment. Effective and affordable health care depends on the availability of accurate, reliable and clinically valid tests. The absence of suitable tests can lead to misdiagnosis with patients potentially receiving insufficient or unnecessary treatment, experiencing delays in treatment or no treatment when treatment is needed.

Identification of pathognomonic gene changes is of particular utility when diagnosing tumours on limited biopsy material and can impart greater diagnostic certainty without the need for more invasive biopsy and attendant increased costs and risks to the patient. The use of such assays can also decrease the risk of misdiagnosis.

In lymphoma diagnosis, identification of specific molecular aberrations provides important prognostic information i.e. the detection of a genetic ‘double hit’ with MYC gene rearrangements and another molecular change such as BCL2 or BCL6 gene rearrangement will influence the use of more aggressive chemotherapy due to the poor prognosis of these combined molecular aberrations. There were 4978 patients diagnosed with NHL and 1,522 deaths from NHL in 2013. Diffuse large B-cell lymphoma (DLBCL) accounts for 30-40% of all NHL cases. Double hit lymphoma is an uncommon subtype accounting for approx. 5% of DLBCL cases (Leukaemia Foundation).

Currently patients are required to self-fund this testing, introducing inequity of access on financial grounds.

Multiple Myeloma

Specific gene rearrangements, mutations and/or copy number changes are seen in a range of neoplasms and detection of these changes has become best practice to determine diagnosis, prognosis and for the appropriate selection of treatment of plasma cell myeloma.

Effective and affordable health care depends on the availability of accurate, reliable and clinically valid tests. The absence of suitable tests can lead to misdiagnosis with patients potentially receiving unnecessary treatment, experiencing delays in treatment or no treatment when treatment is needed.

Identification of pathognomonic gene changes is of particular use when diagnosing tumours on limited biopsy material and can impart greater diagnostic certainty without the need for more invasive biopsy and attendant increased costs and risks to the patient. The use of such assays can also decrease the risk of misdiagnosis.

These molecular aberrations are particularly characteristic of “rare” and less common cancers which have disproportionately higher mortality rates compared to common cancers. Rare and less common cancers are the leading cause of death in children under 15 years of age, constitute the fourth most common cause of death in the 20-39 age group and as a group are the leading cause of death in 40-59 year olds accounting for 52% of all cancer deaths, more than double the impact of coronary heart disease alone. In the 60-69 age group, rare and less common cancers as a group are the leading cause of cancer death. As the Australian population continues to age, these numbers are set to increase.

Research using molecular and genomic techniques has and continues to identify somatic changes in genes that are associated with specific types of tumours resulting in more accurate classification and diagnosis. With increasing numbers of tumour diagnoses made on small tissue and fine needle aspirate biopsies, the detection of a pathognomonic genetic aberration can provide critical information to make the correct diagnosis, without the need for repeat biopsy, more invasive surgical biopsy (and resultant increased risk of complication or morbidity) and ultimately ensure optimal management and the best outcome for patients.

In plasma cell myeloma the genetic translocation t(4;14)(p16;q32) is recognised as a marker of more aggressive disease. However, it has been demonstrated that the prognosis for these patients may be improved with therapies containing bortezomib-based combinations (Fonseca, 2009).

Fonseca R, Bergsagel PL, Drach J, et al. International Myeloma Working Group molecular classification of multiple myeloma: spotlight review. *Leukemia*:2009;23(12):2210-21. [International Myeloma Working Group molecular classification of multiple myeloma: spotlight review.](#)

Non-Hodgkin Lymphoma

Specific gene rearrangements, mutations and/or copy number changes are seen in a range of neoplasms and detection of these changes has become best practice to test NHL:

- MYC gene rearrangement for diagnosis and appropriate selection of treatment of Burkitt lymphoma
- CCD1 and CCD2 characterisation for diagnosis and appropriate selection of treatment of MCL.
- i(7q) chromosomal aberration for diagnosis and appropriate selection of treatment of HSTCL.
- DUSP22 and TP63 characterisation for diagnosis and appropriate selection of treatment of systemic ALK-negative ALCL.
- TCL1A or MTCP1 gene rearrangements for diagnosis and appropriate selection of treatment of TCPL.

Effective and affordable health care depends on the availability of accurate, reliable and clinically valid tests. The absence of suitable tests can lead to misdiagnosis with patients potentially receiving unnecessary treatment, experiencing delays in treatment or no treatment when treatment is needed. Identification of pathognomonic gene changes is of particular use when diagnosing tumours on limited biopsy material and can impart greater diagnostic certainty without the need for more invasive biopsy and attendant increased costs and risks to the patient. The use of such assays can also decrease the risk of misdiagnosis.

These molecular aberrations are particularly characteristic of “rare” and less common cancers, which have disproportionately higher mortality rates compared to common cancers. Rare and less common cancers are the leading cause of death in children under 15 years of age, constitute the fourth most common cause of death in the 20-39 age group and as a group are the leading cause of death in 40-59 year olds accounting for 52% of all cancer deaths, more than double the impact of coronary heart disease alone. In the 60-69 age group, rare and less common cancers as a group are the leading cause of cancer death. As the Australian population continues to age, these numbers are set to increase.

- 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:**

Diffuse Large B Cell Lymphoma

Patients diagnosed with DLBCL at the time of histopathological or morphological review of tumour material would be eligible for this service.

Multiple Myeloma

Patients diagnosed with plasma cell myeloma at the time of histopathological or morphological review of tumour material would be eligible for this service.

Non-Hodgkin Lymphoma

Patients diagnosed with these diseases at the time of histopathological or morphological review of tumour material would be eligible for this service.

- 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):**

The clinical management pathway would be identical to current lymphoma or plasma cell myeloma investigation and treatment:

Patient presentation to general or specialist medical practitioner with symptoms suggestive of lymphoma or plasma cell myeloma.

Patient is referred for investigation including radiology and pathology.

Pathology investigation (FNAB, core or lymph node resection biopsy, tumour resection, etc.)

See Appendix A Flowcharts

PART 6b – INFORMATION ABOUT THE INTERVENTION

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

Diffuse Large B Cell Lymphoma

A test of tumour tissue (including bone marrow) from a patient diagnosed with DLBCL to detect structural gene rearrangements in MYC, BCL2 and BCL6 genes. Testing methods include in situ hybridization (ISH), polymerase chain reaction (PCR) and next generation sequencing (NGS) methodologies among others.

Multiple Myeloma

A test of tumour tissue from a patient diagnosed with plasma cell myeloma to detect mutations, changes in gene copy number or structural gene rearrangements in tumour tissue or bone marrow or blood.

Testing methods include In situ hybridization (ISH), polymerase chain reaction (PCR) and next generation sequencing (NGS) methodologies among others.

Non-Hodgkin Lymphoma

A test of tumour tissue from a patient diagnosed with NHL for i(7q), CCD1 and CCD2, DUSP22 and TP63.

Testing methods include In situ hybridization (ISH), polymerase chain reaction (PCR) and next generation sequencing (NGS) methodologies among others.

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

Not applicable

- 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):**

Diffuse Large B Cell Lymphoma

Testing should be pathologist determinable (able to be requested after a diagnosis of DLBCL is made) in order to provide definitive diagnosis/classification. Retrospective testing could also be requested by a treating clinician and performed on archival material.

There is no role for repeat testing to monitor disease.

Multiple Myeloma

Testing would be provided as requested by the referring medical practitioner for patients with plasma cell myeloma requiring further classification after initial tissue pathology or haematological investigation.

Further testing may be provided after therapy for monitoring of disease.

Non-Hodgkin Lymphoma

Testing would be provided as requested by the referring medical practitioner for patients with NHL requiring further classification after initial tissue pathology or haematological investigation. Further testing may be provided after therapy for monitoring of disease.

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:

Approved Pathologists in Accredited Pathology testing laboratories

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:

Approved Pathologists in Accredited Pathology testing laboratories

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:

Approved Pathology Practitioners as defined in the MBS for Pathology Items

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

- Inpatient private hospital
- Inpatient public hospital
- Outpatient clinic
- Emergency Department
- Consulting rooms
- Day surgery centre
- Residential aged care facility
- Patient's home
- Laboratory
- Other – please specify below

Specify further details here

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

Not applicable

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

- Yes
- No – please specify below

Specify further details here

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):**

Diffuse Large B Cell Lymphoma

There are no current MBS services for this service. The comparator is therefore tissue pathology without complete classification (i.e. incomplete diagnosis and prognostic assessment of disease). Assessment by immunohistochemistry (IHC) may be partially informative, but cannot provide accurate identification of double-hit lymphomas (Argarwal, 2015)

Multiple Myeloma

There are no current MBS services for this service. The comparator is therefore tissue pathology or haematological investigation without complete classification (i.e. incomplete diagnosis and prognostic assessment of disease and ineffective assessment of minimal residual disease). Detection of somatic gene rearrangements, copy number aberrations and/or mutations would be required in addition to tissue pathology and/or haematological investigations but without further health care resources for obtaining the tumour tissue (i.e. on the same specimen).

Non-Hodgkin Lymphoma

There are no current MBS services for this service. The comparator is therefore tissue pathology or haematological investigation without complete classification (i.e. incomplete diagnosis and prognostic assessment of disease and ineffective assessment of minimal residual disease). Detection of somatic gene rearrangements, copy number aberrations and/or mutations would be required in addition to tissue pathology and/or haematological investigations but without further health care resources for obtaining the tumour tissue (i.e. on the same specimen).

- 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 item numbers below)

No

Diffuse Large B Cell Lymphoma

65084; 65087; 72830; 72846-72850; 73049; 73059; 73062; 73063; 73066; 73067

These codes encompass bone marrow biopsy, tissue biopsy (level 5) and cytology fine needle aspiration biopsies.

Multiple Myeloma

Non-Hodgkin Lymphoma

65084; 65087; 72813; 72816; 72817; 72818; 72823; 72824; 72825; 72826; 72827; 72828; 72830; 72836; 72838;

- 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):**

Diffuse Large B Cell Lymphoma

The clinical management pathway after the comparator is the selection of DLBCL therapy based on histological diagnosis using current methods (routine histology and IHC).

Double hit DLBCL is not identified accurately by IHC. Selection of therapy is made on incomplete information. This may result in inappropriate therapy and patient harm.

Multiple Myeloma

The clinical management pathway after the comparator is the selection of plasma cell myeloma therapy based on histological diagnosis using current methods. Molecular subtypes are not identified completely. Selection of therapy is made on incomplete information. Inappropriate treatment may be selection resulting in ineffective therapy or patient harm.

Non-Hodgkin Lymphoma

The clinical management pathway after the comparator is the selection of cancer therapy based on histological diagnosis using current methods. Molecular subtypes are not identified completely. Selection of therapy is made on incomplete information. Inappropriate treatment may be selection resulting in ineffective therapy or patient harm.

See Appendix A Flowcharts

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

- Yes
 No

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

Diffuse Large B Cell Lymphoma

Detection of gene rearrangements in MYC, BCL2 and BCL6 would be required in addition to current service/comparator (tissue histology and immunohistochemistry) for the diagnosis of double-hit DLBCL.

Multiple Myeloma

Non-Hodgkin Lymphoma

Detection of somatic gene rearrangements, copy number aberrations and/or mutations would be required in addition to current service/comparator.

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):

Diffuse Large B Cell Lymphoma

Pathological investigation of lymphoma diagnosed as DLBCL will be extended to assess whether there is a “double hit” rearrangement of MYC gene plus BCL2 or BCL6. Decisions on the most appropriate chemotherapy will be informed by this information.

Multiple Myeloma

Pathological investigation of tumour tissue will be extended to provide further diagnostic and prognostic information. Therapeutic interventions for plasma cell myeloma the patient by surgery, chemotherapy and/or radiotherapy may be affected by this information.

Non-Hodgkin Lymphoma

Pathological investigation of tumour tissue will be extended to provide further diagnostic and prognostic information. Therapeutic interventions for the patient with subtypes of NHL by chemotherapy and/or radiotherapy may be affected by this information.

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):**

Diffuse Large B Cell Lymphoma

Currently, there is no MBS, other public funding or private health insurance for this medical service. The identification of gene rearrangements involving MYC and/or BCL2 and BCL6 in diffuse large B cell lymphomas is necessary for accurate classification and critically informs the choice of appropriate chemotherapy.

Multiple Myeloma

Non-Hodgkin Lymphoma

Currently, there is no MBS, other public funding or private health insurance for this medical service. Tissue pathology (H&E and IHC) and standard haematology testing often require additional molecular investigations for a range of rare and difficult to diagnose cancers. Detection of somatic gene rearrangements, copy number aberrations and/or mutations are recommended locally and internationally as best practice for the diagnosis of plasma cell myeloma/NHL, the appropriate selection of treatment, indicating disease prognosis and monitoring therapeutic outcomes.

The identification of pathognomonic gene changes is of particular use when diagnosing tumours on limited biopsy material and can impart greater diagnostic certainty without the need for more invasive biopsy and other investigation and/or staging tests which may be invasive (e.g. endoscopy/bone marrow trephine) and attendant increased costs and risks to the patient. The use of such assays can also decrease the risk of misdiagnosis and subsequent negative outcomes for the patient undergoing inappropriate treatment.

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

- Superiority
 Non-inferiority

- 45. Below, 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:**

Safety Outcomes:

Diffuse Large B Cell Lymphoma

The proposed test involves equivalent safety issues to current tissue pathology and haematology investigations.

The absence of suitable tests can lead to inappropriate classification of the lymphoma, with the patient potentially receiving either inadequate or inappropriate treatment with poorer outcome.

Multiple Myeloma

Non-Hodgkin Lymphoma

The proposed test involves equivalent safety issues to current tissue pathology and haematology investigations.

The absence of suitable tests can lead to misdiagnosis with patients potentially receiving unnecessary treatment, experiencing delays in treatment or no treatment when treatment is needed.

Clinical Effectiveness Outcomes:

Effective and affordable health care depends on the availability of accurate, reliable and clinically valid tests.

Providing the right treatment to the right patient at the right time depends on meaningful tests proven to impact clinical decisions, integrated with the most current data relevant to the practice of medicine, and recognized as medically necessary to tailor treatment for the unique biology of a disease.

Diffuse Large B Cell Lymphoma

In lymphoma diagnosis, identification of specific molecular aberrations provides important prognostic information by the detection of a genetic “double hit” with MYC gene rearrangements and another molecular change such as BCL2 or BCL6 gene rearrangement will influence the use of more aggressive chemotherapy due to the poor prognosis of lymphoma with these combined molecular aberrations.

Failure to accurately determine the DLBCL status may lead to undertreatment and poorer clinical outcome. Conversely, inappropriate treatment overtreatment of a patient with DLBCL which lacks the double-hit pattern could lead to unnecessary morbidity.

Assessment of the presence of gene rearrangements in MYC, BCL2 and BCL6 requires molecular testing on the tissue sample.

Multiple Myeloma

These molecular aberrations are particularly characteristic of rare and less common cancers, which have disproportionately higher mortality rates compared to common cancers. Many of these rare cancers occur in younger patients who account for 95% of cancer deaths reported in children under 15 years. Accurate diagnosis of rare cancers is difficult for nonspecialised pathologists and can result in inappropriate medical management. Second opinions are recommended to ensure diagnostic accuracy but can introduce delays in the reporting process. Characterisation of pathognomonic genetic abnormalities would expedite the diagnostic process for many rare cancers.

It has been demonstrated that the prognosis for plasma cell myeloma patients with the genetic translocation t(4;14)(p16;q32) have a more aggressive disease. Prognosis may be improved with appropriate therapies e.g. bortezomib-based combinations.

Non-Hodgkin Lymphoma

These molecular aberrations are particularly characteristic of rare and less common cancers, which have disproportionately higher mortality rates compared to common cancers. Many of these rare cancers occur in younger patients who account for 95% of cancer deaths reported in children under 15 years. Accurate diagnosis of rare cancers is difficult for nonspecialised pathologists and can result in inappropriate medical management. Second opinions are recommended to ensure diagnostic accuracy but can introduce delays in the reporting process. Characterisation of pathognomonic genetic abnormalities would expedite the diagnostic process for many rare cancers.

Burkitt, MCL, HSTCL, ALK negative ALCL and TCPL are rare subtypes of NHL with poorer prognosis with conventional chemotherapies. Differential identification allows for allocation of appropriate intensive therapy for each subtype.

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

Diffuse Large B Cell Lymphoma

The incidence of Non-Hodgkin Lymphoma (NHL) in Australia in 2017 is 21.5 per 100,000 people with 4,978 diagnoses of NHL in 2013. (AIHW 2017 Australian Cancer Incidence and Mortality (ACIM) book for Non-Hodgkin Lymphoma).

DLBCL accounts for 30-40% of these cancers (Leukaemia Foundation) therefore the population is between 1493 and 1991, a median of 1742 patients.

Multiple Myeloma

The prevalence of plasma cell myeloma in Australia is 7.1 per 100,000 people with 1637 new cases diagnosed in 2013 (AIHW).

Australian Institute of Health and Welfare 2017 Australian Cancer Incidence and Mortality (ACIM) book for Multiple Myeloma.

Non-Hodgkin Lymphoma

The incidence of Non-Hodgkin Lymphoma (NHL) in Australia in 2017 is 21.5 per 100,000 people with 4,978 diagnoses of NHL in 2013. (AIHW 2017 Australian Cancer Incidence and Mortality (ACIM) book for Non-Hodgkin Lymphoma).

Most would not require further subtyping but it is estimated that 15% would require somatic tumour gene characterisations (Burkitt 2%, MCL 6%, PTCL 7% and ALCL 1%). The incidence of T cell lymphocytic leukaemia is rare, approx. 2% of mature lymphocytic leukemias in adults. An estimated population would be less than 25.

Therefore, the proposed population is 800 per annum.

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

Diffuse Large B Cell Lymphoma

Once

Once for diagnosis/classification, either at time of initial diagnosis (pathologist determinable) or upon retrospective clinician request of not previously performed.

Multiple Myeloma

Once

On average once for diagnosis and once per year for minimal residual disease assessment.

Note: not all cancer patients are treated with surgery, some may have multiple surgeries, but most would not have surgery once per year and only a minority of patients may require minimal residual disease using genetic investigations, therefore once per year is a reasonable average estimate.

Non-Hodgkin Lymphoma

Once for diagnosis

On average once per year expected for minimal residual disease assessment (pathologist-determinable).

Note: Only a minority of patients with lymphoma may require minimal residual disease using genetic investigations, therefore once per year is a reasonable average estimate.

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

Diffuse Large B Cell Lymphoma

Once

One test per DLBC lymphoma diagnosis

Multiple Myeloma

Five

Note: not all cancer patients are treated with surgery, some may have multiple surgeries, but most would not have surgery every year for five years therefore five years is a reasonable maximum estimate.

Non-Hodgkin Lymphoma

Five

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

Diffuse Large B Cell Lymphoma

1700

The median number of DLBCL diagnoses is a reasonable estimate of patients who will utilise the proposed medical service for the first full year.

Multiple Myeloma

1800

Non-Hodgkin Lymphoma

800

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:

Diffuse Large B Cell Lymphoma

Uptake in the next three years will result in all of the at-risk population (patients with DLBCL) receiving testing as part of the initial diagnosis/classification process.

This testing is already being performed in a subset of patients on a self-funded basis. A small number of patients who have relapsed who were not tested at the time of NHL diagnosis may require testing. In some circumstances, this may be possible using retrospective testing on archival material. This is estimated to represent <10% of the total number of patients tested.

AIHW statistics indicate that rate of NHL is relatively stable. Therefore, the projected number of patients will remain at less than 2000 per year for the next three years.

Leakage to populations not targeted by the service will be constrained by the MBS item number descriptors to ensure testing is applied only where clinically indicated.

Multiple Myeloma

Uptake in the next three years will result in all of the at risk population using the test in diagnosis.

AIHW statistics indicate that incidence of plasma cell myeloma is likely to rise to 1816 in 2017 and 1876 in 2018. Therefore, the projected number of patients is likely to remain at less than 2000 per year for the next three years.

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

Non-Hodgkin Lymphoma

Uptake in the next three years will result in all of the at-risk population receiving testing as part of the initial diagnosis/classification process.

AIHW statistics indicate that rate of NHL is relatively stable. Therefore, the projected number of patients will remain at less than 850 per year for the next three years.

Leakage to populations not targeted by the service will be constrained by the MBS item number descriptors to ensure testing is applied only where clinically indicated.

PART 8 – COST INFORMATION

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

Equipment and resources	Diffuse Large B Cell Lymphoma	Multiple Myeloma	Non-Hodgkin Lymphoma
FISH kit, probes, reagents, ancillary reagents	\$350.00	\$450.00	\$350.00
Labour medical (consultant pathologist)	\$50.00	\$75.00	\$50.00
Labour scientific	\$40.00	\$60.00	\$40.00
Labour on costs	\$14.00	\$15.00	\$14.00
Total per test	\$454.00	\$600.00	\$454.00

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

7 -10 working days

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.

<p>Category 6 –Genetics P7</p> <p>Proposed item descriptor</p> <p>Detection of gene rearrangements in MYC, BCL2 and BCL6 in a patient with Diffuse Large B Cell Lymphoma</p> <p>OR</p> <p>Identification of the following genetic abnormalities in Non-Hodgkin Lymphoma:</p> <ul style="list-style-type: none"> • MYC gene rearrangement for the diagnosis of Burkitt Lymphoma, AND/OR • one or more of CCND1 and CCND2 gene rearrangements for the diagnosis of Mantle Cell Lymphoma, AND/OR • i(q7) for the diagnosis of Hepatosplenic T-cell Lymphoma (Peripheral T-cell NHL) • DUSP22 and TP63 gene rearrangements for the diagnosis of ALK negative Anaplastic Large Cell Lymphoma, AND/OR • one or more TCL1A or MTCP1 gene rearrangements in a patient with T-cell Prolymphocytic Leukaemia. <p>Fee: \$454 (for each)</p> <p>OR</p> <p>Detection of chromosome translocations t(4;14), t(14;16), t(14;20) copy number changes 1q gain and 17p deletion in in the assessment of plasma cell myeloma.</p> <p>Fee: \$600</p>
--

PART 9 – FEEDBACK

The Department is interested in your feedback.

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

Insert approximate duration here

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

- Yes
- No

(b) If no, provide areas of concern:

Describe areas of concern here

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

- Yes
- No

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

Insert feedback here

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?

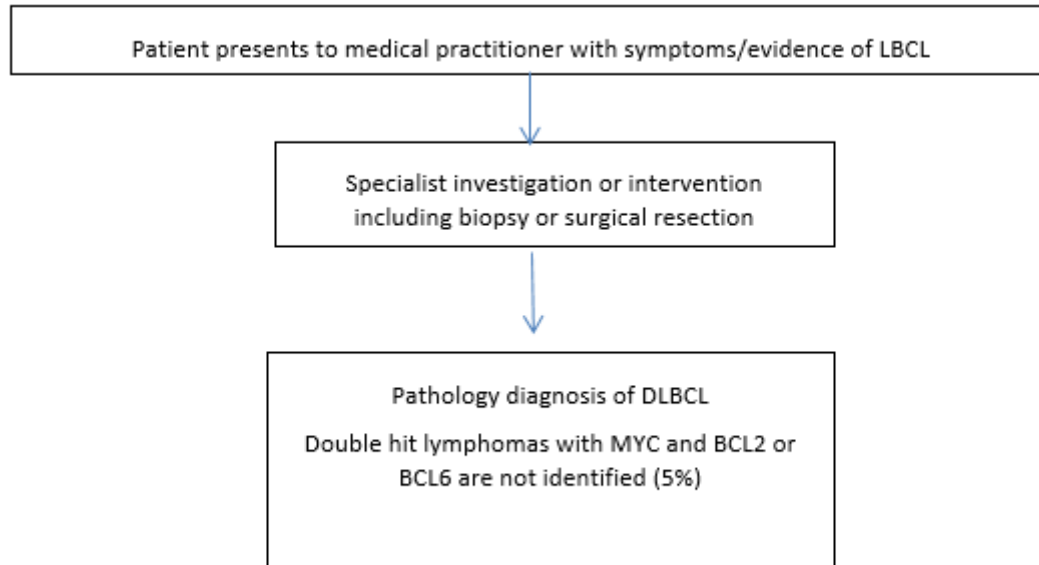
- Yes
- No

(b) If yes, please advise:

Insert feedback here

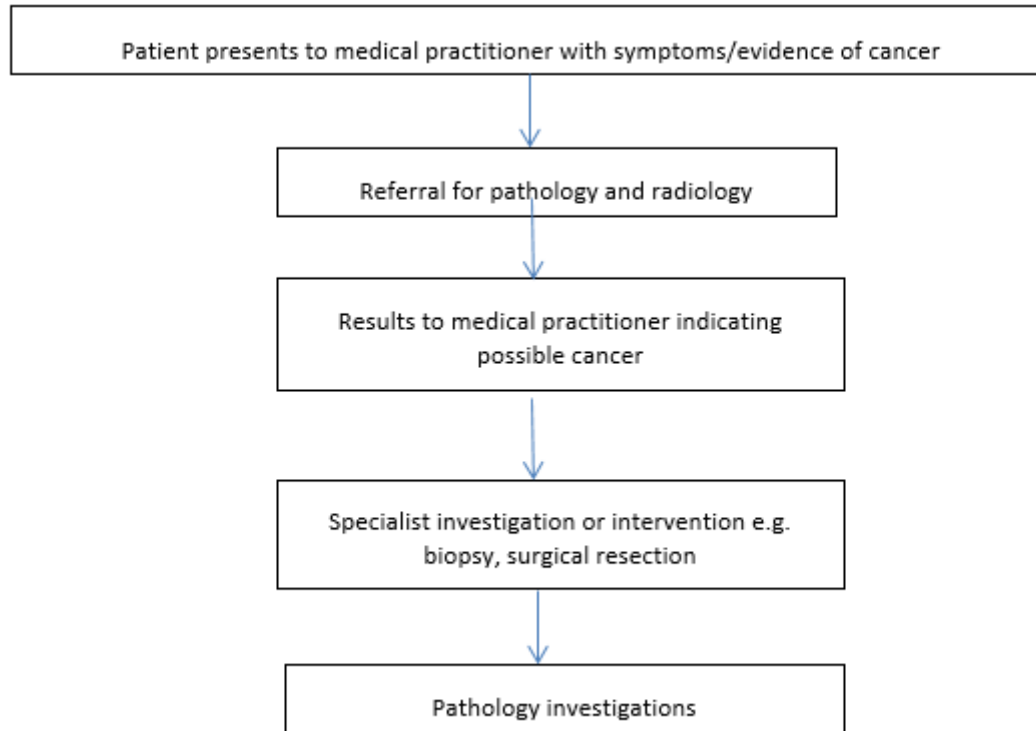
Appendix A Flowcharts

Q26 Current clinical pathway before proposed medical service

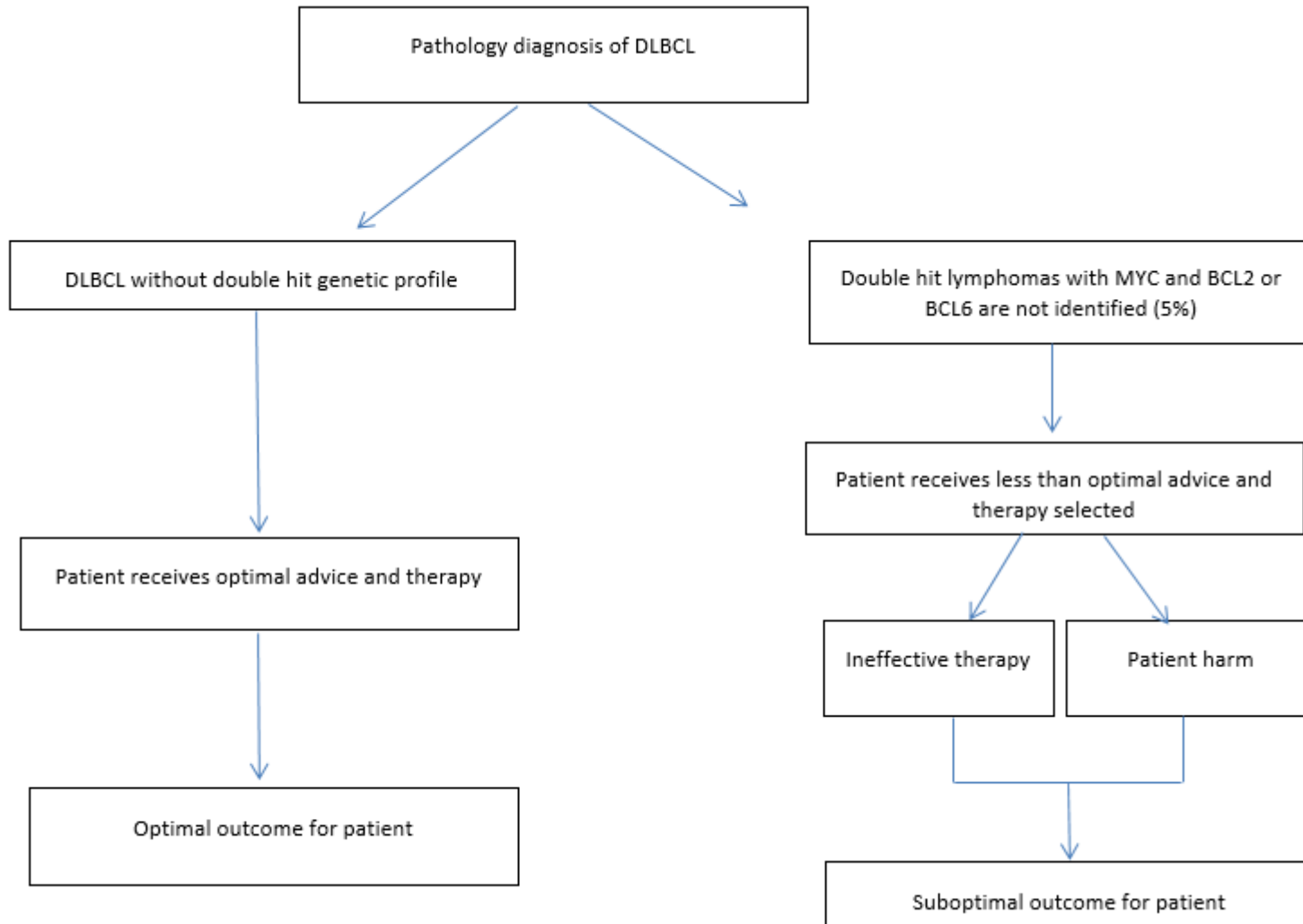


Appendix A Flowcharts

Q26 Clinical pathway before intervention



Q40 Current clinical pathway after comparator



40 Clinical pathway after comparator (current)

