Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1526 – Somatic gene testing of haematological malignancies

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

Date of MSAC consideration: MSAC 76th Meeting, 1-2 August 2019

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

1. Purpose of application

An application for genetic testing for the diagnosis of a specified number of lymphoid neoplasms, and for prognostic testing in patients with myeloma, was received from the Royal College of Pathologists in Australasia (RCPA) by the Department of Health.

The proposed medical services would provide genetic testing for:

- detection of gene rearrangements in *MYC*, *BCL2* and/or *BCL6* in the diagnosis of a patient with diffuse large B-cell lymphoma or high-grade B-cell lymphoma
- identification of *MYC* gene rearrangement for the diagnosis of Burkitt lymphoma
- identification of one or more of *CCND1* and *CCND2* gene rearrangements for the diagnosis of mantle cell lymphoma
- identification of isochromosome 7q for the diagnosis of hepatosplenic T-cell lymphoma
- identification of *DUSP22* and *TP63* gene rearrangements for the diagnosis of *ALK*-negative anaplastic large cell lymphoma
- identification of one or more *TCL1A* or *MTCP1* gene rearrangements in the diagnosis of a patient with T-cell prolymphocytic leukaemia
- detection of chromosome translocations t(4;14), t(14;16), t(14;20), copy number changes 1q gain and 17p deletion in the initial assessment of plasma cell myeloma.

This application was considered in conjunction with Applications 1527 and 1528.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, MSAC supported 17 of the 19 requested MBS items proposed by the MSAC Executive overall; all items in this application were supported. Two requested MBS items were deferred, relating to hydatidform mole (in application 1528) and analogue secretory carcinoma (in application 1528), in order to seek more information to clarify the appropriate test usage and item descriptor wording.

Consumer summary

Cancer arises when cells develop genetic changes that cause abnormal growth. A somatic cell is any cell in the body that is not an egg or sperm cell, and gene mutations which develop in cells after the egg is fertilised are called "somatic mutations". Somatic tumour testing involves testing a piece of tumour to look for somatic mutations in the cancer cells. These tests can help provide patients with an appropriate diagnosis.

Applications 1526, 1527 and 1528 are for somatic tumour testing for rare cancers. They have been grouped together because the numbers of patients with each of these cancers is too small to consider each application on its own.

MSAC's recommendation to the Commonwealth Health Minister

MSAC recommended some changes to the wording in the MBS item descriptors, to ensure consistency and appropriate setting of fees when testing for these somatic gene mutations.

MSAC supported the following listings for Application 1526:

Category 6 – (Group P7 Genetics) – Pathology services
XXXXX-01 Analysis of tumour tissue from a patient with clinical or laboratory evidence , including morphological features, of diffuse large B cell lymphoma or high grade B-cell lymphoma, as requested by a specialist or consultant physician, for the characterisation of gene rearrangements in the following, where MYC Immunohistochemistry is non-negative. a) *MYC*; and b) *BCL2*; and/or *c)* *BCL6.* Maximum one test per lifetime Fee: $400 Item not to be claimed with XXXXX-02
XXXXX-02 Analysis of tumour tissue from a patient with clinical or laboratory evidence, including morphological features, of Burkitt lymphoma, as requested by a specialist or consultant physician, for the characterisation of *MYC* gene rearrangement. Maximum one test per lifetime Fee: $340 Item not to be claimed with XXXXX-01
XXXXX-03 Analysis of tumour tissue from a patient with clinical or laboratory evidence, including morphological features, of mantle cell lymphoma, as requested by a specialist or consultant physician, for the characterisation of gene rearrangement in one or more of the following : a) *CCND1*; or b) *CCND2*. Maximum one test per lifetime Fee: $400

Category 6 – (Group P7 Genetics) – Pathology services
XXXXX-04 Analysis of tumour tissue from a patient with clinical or laboratory evidence, including morphological features, of hepatosplenic T-cell lymphoma, as requested by a specialist or consultant physician, for the presence of isochromosome 7q. Maximum one test per lifetime Fee: $340
XXXXX-05 Analysis of tumour tissue from a patient with clinical or laboratory evidence, including morphological features, of ALK negative anaplastic large cell lymphoma, as requested by a specialist or consultant physician, for gene rearrangements in one or more of the following: a) *DUSP22*; or b) *TP63*. Maximum one test per lifetime Fee: $400
XXXXX-06 Analysis of blood or bone marrow from a patient with clinical or laboratory evidence, including morphological features, of T-cell prolymphocytic leukaemia, as requested by a specialist or consultant physician, for gene rearrangements in one or more of the following: a) *TCL1A*; or b) *MTCP1*. Maximum one test per lifetime Fee: $400
XXXXX-07 Analysis of blood or bone marrow from a patient with clinical or laboratory evidence, including morphological features, of plasma cell myeloma, as requested by a specialist or consultant physician, for the characterisation of the following gene rearrangements: a) Chromosome translocations t(4;14), t(14;16), t(14;20) and b) 1q gain and c) 17p deletion Maximum one test per lifetime Fee: $500

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

MSAC noted that the proposals for 19 new MBS items from the MSAC Executive spanned three applications:

- Application No. 1526 – Somatic gene testing of haematological malignancies
- Application No. 1527 – Somatic gene testing of central nervous system tumours and sarcomas
- Application No. 1528 – Somatic gene testing of hydatidiform mole, granulosa cell tumour of the ovary, midline squamous cell carcinoma, salivary gland carcinoma, secretory carcinoma of the breast and renal cell carcinoma.

MSAC noted that there has been a long history of meetings for these applications. The requested MBS items are for rare tumours with low mutation frequencies, so they have been pragmatically grouped together.

MSAC affirmed the importance of ensuring that appropriate quality assurance programs are established for all gene testing methods as part of the implementation of the proposed MBS items.

MSAC noted that its task is to ensure that each item descriptor is appropriate for the purpose for which it is intended. The RCPA has had its feedback already incorporated into the proposed descriptors.

MSAC advised the following as being applicable across all relevant MBS items:

- for testing for a rearrangement in a single gene, the fee should be $340 (reflecting a slightly higher fee than the MBS item number for ISH for HER2 and in doing so establishing a benchmark); for a panel testing of 2–3 genes, the fee should be $400 (reflecting the lowest requested fee for testing 3 genes); and for a panel testing of 4 or more genes, the fee should be $800 (reflecting the lowest requested fee for testing 4 or more genes)
- if a descriptor is referring to a single gene, then write the gene into the text (not in a bulleted list)
- if it is referring to more than one gene, then write the genes in a list without the word "or" between each gene
- change "characterisation of one or more of the following gene rearrangements" to "characterisation of gene rearrangements in one or more of the following" and remove the word "or" between each gene in the list that follows
- change "mutation" to "pathogenic variant"
- state that there is a maximum of one test per lifetime.

In addition to the above changes, the following specific amendments were proposed:

- XXXXX-01 – "laboratory evidence" should be defined as being "not negative on immunohistochemistry"
- XXXXX-01 – this item cannot be co-claimed with XXXXX-02, so a note to this effect should be added
- XXXXX-02 – this item cannot be co-claimed with XXXXX-01, so a note to this effect should be added
- XXXXX-04 – change "the characterisation of i(q7) gene rearrangement" to "the presence of isochromosome 7q"
- XXXXX-08 – keep "glioma or glioneural tumours" (not "oligodendroglioma") and use "detection" instead of "characterisation"
- XXXXX-13 – the fee should be benchmarked to the fee of $250 (reflecting MBS items 73348 and 73350, which both specify the detection of known gene variants in diagnosing cystic fibrosis), and "characterisation" should be replaced with "detection".

MSAC noted the Department's concerns that the proposed descriptor for XXXXX-11 does not limit the number of genes that may be tested. While this permits the testing of a greater

number of clinically relevant genes, this descriptor may lead to a risk of leakage for testing of gene mutations where there is no evidence of clinical utility. However, MSAC noted that a panel test will be required in most cases, and the costing of testing extra genes should not result in an increase beyond the recommended fee of $800.

MSAC considered that XXXXX-17 appears to be a duplicate of XXXXX-15 for analogue secretory carcinoma, so needs to be amended to clarify the intended difference.

MSAC considered that XXXXX-12 for hydatidiform mole should be re-visited because it did not adequately address either the likelihood of recurring disease needing repeat testing (and thus the increased possibility of false negative clinical conclusions) or the need for samples from the parental source.

MSAC advised that, as a general principle, these tests are performed once in a lifetime. It was noted that some might patients may need another test if metastasis is present; however, MSAC did not support these items being used for monitoring. It is possible that, on relapse, retesting may be desirable. MSAC advised that this should not be accommodated now because MSAC could not support the consequential delay in implementing these applications for initial diagnosis.

4. Background

An application for MBS funding of the requested genetic tests has not previously been made to the Medical Services Advisory Committee (MSAC).

Applications 1526, 1527 and 1528 were created from an earlier, larger application 1459 (now retired), submitted by the RCPA in November 2017. Application 1526 seeks public funding for somatic testing of tumour tissue in patients grouped as haematological malignancies.

A PICO Confirmation was created for each of the three applications, and discussed at the PASC meeting of 12 April 2018. The PASC discussion highlighted that, at that time, the three applications did not adequately address the clinical utility of each requested genetic test.

Following this PASC outcome, and consideration by the MSAC Executive in June 2018, the Department and the Applicant, together with other stakeholders, convened a meeting on 16 May 2019, the "Pathology Pilot Meeting". Amongst other things, this workshop considered each application, to determine the clinical utility of each of the separate tests, and their place in current clinical practice. To facilitate this discussion, and explore how best to identify the type and nature of the clinical utility of future requests for MBS funding of genetic tests, the workshop was guided by an approach developed by Medex Consulting (provided to the MSAC Executive at its meeting of 3 May 2019). Ahead of the workshop, a triage table of expected clinical utility type(s) was drafted encompassing each requested test. Based on feedback before and after the workshop, this table was updated for each of the requested tests and incorporates the advice of Medex Consulting, the applicant, other stakeholders, and the Department.

At this workshop, the Department proposed that the application would be considered for expedition through the MSAC process if the MSAC Executive was also agreeable with this approach.

Current funding arrangements
The genetic tests proposed in the application are currently provided by the States and Territories, often being conducted through public hospital genetic services or otherwise

through private pathology providers. Currently, private patients are asked to self-fund these tests.

5. Prerequisites to implementation of any funding advice

Neither the PICO nor the MSAC Executive discussion addressed the regulatory and/or accreditation requirements associated with the provision of any of the proposed tests.

6. Proposal for public funding

The PASC process was used for this application, but given the status of testing in the Australian context, the nature of the genetic tests proposed, and following discussions both at the Pathology Pilot Meeting and by the MSAC Executive, a full HTA assessment was not undertaken.

The requested MBS item descriptors are presented in Table 1. The item descriptors suggested by the Department are presented in Table 2.

Table 1: Requested MBS item descriptors, per the application form

Category 6 –Genetics P7
Detection of gene rearrangements in MYC, BCL2 and BCL6 in a patient with Diffuse Large B Cell Lymphoma or high-grade B-cell lymphoma **OR** Identification of the following genetic abnormalities in Non-Hodgkin Lymphoma: • 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. Fee: $454 (for each) **OR** 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. Fee: $600

Table 2: Department-suggested MBS item descriptors

Category 6 –Genetics P7
XXXXX-01 Analysis of tumour tissue from a patient with clinical or laboratory evidence of diffuse large B cell lymphoma or high grade B-cell lymphoma, as requested by a specialist or consultant physician, for the characterisation of: one or more of the following gene rearrangements. d) *MYC*; or e) *BCL2*; and/or *f)* *BCL6.* Maximum one test per lifetime Fee: $xxx.xx Benefit: 75% = $xxx.xx 85% = $xxx.xx.

Category 6 –Genetics P7
XXXXX-02 Analysis of tumour tissue from a patient with clinical or laboratory evidence of Burkitt lymphoma, as requested by a specialist or consultant physician, for the characterisation of *MYC* gene rearrangement. Maximum one test per lifetime Fee: $xxx.xx Benefit: 75% = $xxx.xx 85% = $xxx.xx.
XXXXX-03 Analysis of tumour tissue from a patient with clinical or laboratory evidence of mantle cell lymphoma, as requested by a specialist or consultant physician, for the characterisation of one or more of the following gene rearrangements: c) *CCND1*; or d) *CCND2*. Maximum one test per lifetime Fee: $xxx.xx Benefit: 75% = $xxx.xx 85% = $xxx.xx.
XXXXX-04 Analysis of tumour tissue from a patient with clinical or laboratory evidence of hepatosplenic T-cell lymphoma, as requested by a specialist or consultant physician, for the characterisation of i(q7) gene rearrangement. Maximum one test per lifetime Fee: $xxx.xx Benefit: 75% = $xxx.xx 85% = $xxx.xx.
XXXXX-05 Analysis of tumour tissue from a patient with clinical or laboratory evidence of ALK negative anaplastic large cell lymphoma, as requested by a specialist or consultant physician, for the characterisation of one or more of the following gene rearrangements: c) *DUSP22*; or d) *TP63*. Maximum one test per lifetime Fee: $xxx.xx Benefit: 75% = $xxx.xx 85% = $xxx.xx.
XXXXX-06 Analysis of blood or bone marrow from a patient with clinical or laboratory evidence of T-cell prolymphocytic leukaemia, as requested by a specialist or consultant physician, for the characterisation of one or more of the following gene rearrangements: c) *TCL1A*; or d) *MTCP1*. Maximum one test per lifetime Fee: $xxx.xx Benefit: 75% = $xxx.xx 85% = $xxx.xx.
XXXXX-07 Analysis of blood or bone marrow from a patient with clinical or laboratory evidence of plasma cell myeloma, as requested by a specialist or consultant physician, for the characterisation of one or more of the following gene rearrangements: d) Chromosome translocations t(4;14), t(14;16), t(14;20) e) 1q gain f) 17p deletion Maximum one test per lifetime Fee: $xxx.xx Benefit: 75% = $xxx.xx 85% = $xxx.xx.

7. Summary of public consultation feedback/consumer issues

There was no external consultation sought for this application beyond the stakeholders attending the "Pathology Pilot Meeting" held at the RCPA on 16 May 2019.

8. Proposed intervention's place in clinical management

The most recent version of the World Health Organization classification of lymphoid neoplasms defines the morphological subtypes of this group of cancers and their genetically distinct variants. By virtue of their place in the WHO Guidelines, the proposed genetic tests have documented known significance in each of the diseases specified; there are no tests proposed in the application with variations of unknown significance.

The clinical utility of each test, and the place of each test in a diagnostic algorithm in contemporary Australian practice, were discussed and confirmed by the pathology and haematology specialist physicians at the Pathology Pilot Meeting and with reference to published literature.

The test for *CCND1* and *CCND2* is proposed to be performed following a negative immunohistochemistry (IHC) assessment of CCND1.

9. Comparator

The comparator for this application is "no genetic testing" for each of the genetic abnormalities described.

10. Comparative safety

For this application, there was no assessment of the comparative safety of testing. The application stated that, for each investigation "(t)he proposed test involves equivalent safety issues to current tissue pathology and haematology investigations".

Test adverse events
The proposed tests are performed on either a blood, bone marrow or other tissue containing lymphoma, depending on the disease type, which would already have been taken for the purposes of tumour morphological assessment. It is not expected that there would be adverse events directly associated with testing. However, if a sample is insufficient or of too poor quality, a second sample may be required to provide results.

The main downstream effect of the proposed test is to provide a definitive diagnosis for the patient and thus inform subsequent patient interactions and management. Where the test results in a diagnosis associated with a poor prognosis, the test result is expected to be delivered by a specialist physician who can counsel the patient appropriately.

Adverse events from change in management
Among the proposed tests, predictive value for a change in treatment is only anticipated for double/triple hit DLBCL and for the presence of adverse translocation(s) in myeloma.

There are no adverse consequences anticipated from the use of any of the proposed tests. None of the proposed tests are considered experimental, nor is their use anticipated to lead to access to therapies which are not currently approved for use in Australia.

11. Comparative effectiveness

Direct effectiveness
According to the supportive WHO classification in the case of the tests for lymphoid neoplasms, each test has diagnostic and prognostic and/or predictive value, whereas assessment for translocations in patients with myeloma has prognostic value.

Clinical claim

The application stated that the overall clinical claim was for superiority over not testing for each of the genetic defects described.

12. Economic evaluation

The MSAC Executive advised that, in the context of clear clinical utility and low costs of testing overall, a full economic evaluation was not warranted for this application.

13. Financial/budgetary impacts

An epidemiological approach has been used to estimate the financial implications of listing each of the proposed tests on the MBS.

The Australian Institute of Health and Welfare (AIHW) provided complete data on the incidence of non-Hodgkin lymphoma and myeloma for 2015 (data for subsequent years are currently incomplete). The estimate of the incidence of each subtype of lymphoid neoplasm was based on reported proportions of each subgroup in published literature – Table 3.

The AIHW estimate the incidence of non-Hodgkin lymphoma (NHL) at 5031 cases for 2015. The proportion of all NHL that is:

- diffuse large B-cell lymphoma (DLBCL) is 40%[1]
- Burkitt lymphoma (BL) is 2%[3]
- mantle cell lymphoma (MCL) is 10%[3]
- *ALK*-negative anaplastic large cell lymphoma (ALCL) is 1%[3]
- hepatosplenic T-cell lymphoma is 0.12%[2]
- acute prolymphocytic T-cell leukaemia (pTCL) is 4.7%.[3]

Based on complete data for 2015 (data for subsequent years are currently incomplete) the AIHW estimate the incidence of myeloma in Australia at 1885 cases. The proposed myeloma translocation tests should be performed at initial diagnosis.[4] Additional translocation testing may be required at relapse but these tests are not included in this application.

[1] Hoffbrand, A. et al. Postgraduate Haematology (seventh edition) 2016. Wiley Blackwell.
[2] Al-Hamadani, M. et al. Non-Hodgkin lymphoma subtype distribution, geodemographic patterns, and survival in the USA longitudinal analysis of the National Cancer DataBase from 1998 to 2011. American Journal of Hematology 2015; 90(9): 790-795
[3] van Leeuwen, M. Lymphoid neoplasm incidence by WHO subtype in Australia 1982–2006. International Journal of Cancer. 2014; 135(9): 2146-2156
[4] International Myeloma Working Group. IMWG consensus on risk stratification in multiple myeloma. Leukaemia 2014; 28: 269–277

Table 3: Estimated disease incidence and number of tests to be performed annually

Genetic test(s)	Tumour type	Estimated number of new cases per year (n)	Estimated number of tests per year (n)
MYC, *BCL2*, *BCL6*	DLBCL	2012	2012
MYC	BL	101	101
CCND1, *CCND2*	MCL	503	503
DUSP22, *TP63*	*ALK*-negative ALCL	50	50
I(q7)	Hepatosplenic T-cell lymphoma	6	6
TCL1A, *MTCP1*	Acute pTCL	236	236
Translocations	Myeloma	1885	1885

14. MSAC Executive discussion

MSAC Executive key issue	MSAC Executive advice to MSAC
Clinical claim reasonable	The current WHO Guideline on lymphoid neoplasms and IMWG consensus on risk stratification in multiple myeloma provide the appropriate standards of clinical care for Australian patients.
Testing methodology	The MBS item descriptor in the application reasonably did not include a testing method for any of the tests.
Determination of diagnostic performance, clinical validity and clinical utility	The Department and applicant had agreed an approach to the determination of clinical utilities for each of the proposed tests, based on a triage assessment developed prior to, and discussed at, the Pathology Pilot Meeting. The entry of each test in the WHO Guideline was accepted to provide sufficient demonstration of its diagnostic performance, and also its clinical validity and/or clinical utility. Further assessment of these aspects was therefore not sought for this application.
Limitations on number of tests	Each of the tests described are proposed to be performed once per patient lifetime.
Economic evaluation and financial analysis	Given the relatively small patient populations of each disease type who require each genetic test, the estimated fee for each service involving an individual test, and the estimated total annual cost of funding all the tests in the application, it was proposed by MSAC Executive that a full HTA assessment would not be required prior to consideration of funding by MSAC.
Uncertainty with financial inputs	Excepting for myeloma, DLBCL and MCL, given the estimated very low incidence of the tumour types described, and a lack of registry data for each, there may be variability in the number of patients who require testing. However, based on available data, the number of tests per year is not expected to be substantially larger than described.

At its 21 June 2019 teleconference, the MSAC Executive noted that the purpose of the application is to seek Medicare Benefits Schedule (MBS) listing of genetic testing of a selected number of lymphoid neoplasms and myeloma.

The MSAC Executive noted the most recent classification of lymphoid neoplasms by the World Health Organization (WHO)[5], and prognostic classification of myeloma according to the International Myeloma Working Group (IMWG)[6] serve as the current clinical standards for Australian patients. The MSAC Executive accepted that these WHO Guidelines only include genetic biomarkers into their classification when these biomarkers have been shown to have prognostic and/or predictive value.

[5] The 2016 revision of the World Health Organization classification of lymphoid neoplasms. Swerdlow. Blood 2016; Vol 127(20):2375-2390

[6] International Myeloma Working Group. IMWG consensus on risk stratification in multiple myeloma. Leukaemia 2014; 28: 269–277

The MSAC Executive noted that:

- Diffuse large B-cell lymphoma is the commonest sub-type of non-Hodgkin lymphoma and is newly characterised in the WHO Guideline as double-hit or triple-hit according to *MYC*, *BCL2* and/or *BCL6* status.
- Burkitt lymphoma is a rare subtype of non-Hodgkin lymphoma per the WHO Guideline, which is characterised by the presence of the *MYC* gene rearrangement.
- *CCND1* gene rearrangement is seen in up to 35% of all cases of mantle cell lymphoma and has prognostic value. Among those without *CCND1* rearrangements, *CCND2* gene rearrangements are seen in approximately half of all patients; as per the WHO Guideline this test has "diagnostic utility".
- Hepatosplenic T-cell lymphoma is an extremely rare subtype of mature T-cell lymphomas associated with a dismal outcome despite combination chemotherapies. The presence of isochromosome 7q is the commonest chromosomal abnormality seen in this condition and is considered diagnostic.
- The *DUSP22* and *TP63* gene rearrangements are diagnostic and prognostic for *ALK*-negative anaplastic large cell lymphoma.
- In patients with T-cell prolymphocytic leukaemia the gene rearrangements *TCL1A* and/or *MTCP1* are diagnostic for this condition.
- The translocations t(4;14), t(14;16), t(14;20) and copy number changes 1q gain and 17p deletion in plasma cell myeloma are prognostic for worse clinical outcomes.

The MSAC Executive noted that, when used as proposed, each of the tests above would be performed once in an individual patient's lifetime.

The MSAC Executive agreed with the Department's determination of the clinical utility for each of the proposed tests as having been comparatively assessed in published literature, demonstrated by their inclusion in the relevant WHO Guidelines documents.

The MSAC Executive therefore advised that each of the proposed tests offers superior effectiveness and non-inferior safety compared with no testing.

The MSAC Executive also advised that the financial impact analysis was sufficiently accurate to be relied on to inform decision-making.

The Executive noted that the Australian diagnostic definitions of the lymphoid neoplasms in this application are based on the current WHO Guideline. Similarly, the prognostic testing of patients with myeloma in current Australian clinical practice incorporates the utility of the translocation tests proposed in this application, based on peak-body guidance of the IMWG. The Executive noted that the initial application proposed that translocation testing in patients with myeloma be also performed for disease monitoring, but expert opinion confirmed this as not an appropriate use of this test at the Pathology Pilot Meeting.

Given that the WHO Guideline subtypes the lymphoid neoplasms according to tests which are considered to have satisfactory diagnostic performance, the Executive advised that the proposed tests in this application should not be re-examined in this regard.

Given the estimated fee per test, the likely single use of each test per patient lifetime, and the relatively small size of the populations anticipated requiring each test, the MSAC Executive advised that further assessment of the application, including by the Evaluation Sub-Committee would not be necessary and that it could proceed directly to the full MSAC for consideration.

A further discussion on the three applications to finalise the item descriptor wording was held at the MSAC Executive meeting on 16 August 2019.

15. Other significant factors

Nil.

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

The College would like to take this opportunity to thank the Department and the MSAC for their assistance in moving this application forward to a successful outcome that will deliver great benefits for a small group of vulnerable patients. The College is seeking clarification on a number of issues, which may be crucial in the drafting of the item number descriptors.

17. Further information on MSAC

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