Stakeholder Briefing

The new commissioning and funding arrangements for six molecular genetic tests for cancer introduced by NHS England in April 2016

This Stakeholder Briefing has been developed to clarify the new arrangements for commissioning and funding of six molecular diagnostic tests for cancer in the NHS in England for 2016/17.

It aims to provide NHS staff – be they commissioner or hospital provider financial staff, clinicians and pathology staff – with a clear understanding how the new funding arrangements for these tests in 2016/17 will operate to support timely and appropriate patient access.

This Briefing has been prepared by the The Association of the British Pharmaceutical Industry (ABPI), The British In Vitro Diagnostics Association (BIVDA) and Cancer Research UK (CRUK) with the support of the NHS England Specialised Commissioning Team.

Background

Until recently there has been a lack of clarity as to the commissioning responsibility and funding arrangements for molecular testing in the NHS in England. This lack of clarity, principally as to how the funding for these tests sat within the payment system, meant that there was variation in the provision of these tests to patients across the NHS (as hospital pathology departments were unclear as to how these tests would be reimbursed). If patients/clinicians are not accessing the appropriate molecular tests detailed knowledge of a patient's cancer – and therefore the best treatment options for them – remain unknown.

The situation was highlighted in '*Achieving World-Class Cancer Outcomes – a strategy for England 2015-20*' published in 2015 which included Recommendation 37 that '*NHS England should transform access to molecular treatments to guide treatment for cancer*' through nationally commissioning access to molecular diagnostics. Whilst some of the Cancer Strategy recommendations may take time – such as developing plans to move to validated multiplex panel testing - a significant first step has been made by NHS Improvement with the introduction of a clear mechanism for funding of an initial six specific molecular tests for cancer within the 2016/17 National Tariff Payment System (NTPS).

This briefing helps explain how these new processes are working from April 2016.

The National Tariff Payment System 2016-17 and Molecular Diagnostics

The National Tariff Payment System 2016/17 (March 2016) set out the new arrangements for specific molecular tests. The background to the changes was described in the formal Tariff consultation document and the key section is set out below:

Molecular diagnostics

113. *Since our earlier engagement events, NHS England has been looking at ways to support the independent Cancer Taskforce recommendations that the payment system must keep pace with advances in molecular diagnostics by unbundling certain tests from prices for a period of three years.*

114. *Because of the speed of progress in molecular diagnostics, bundling tests into prices may mean that the costs of these tests run ahead of the reference costs that inform national prices. To ensure that the payment system promotes innovation and equitable access, a list of procedures excluded from national prices and reimbursed directly by NHS England in line with mandatory NICE guidance or an approved NHS England clinical treatment policy has been produced.*

115. *It is the intention of NHS England to exclude the cost of the procedures on this list from national prices for three years. We propose to exclude them for 2016/17 and intend to propose their further exclusion in consultation on future tariffs.*

116. *For 2016/17 we are proposing to add the molecular diagnostic tests in the table below to the high cost procedures list.*

Table 6: Molecular Diagnostic Test	NICE Guidance
NRAS/KRAS Testing	**TA 176:** Cetuximab for the first-line treatment of metastatic colorectal cancer
Oncotype DX	**DG 10:** Gene expression profiling and expanded immunohistochemistry tests for guiding adjuvant chemotherapy decisions in early breast cancer management: MammaPrint, Oncotype DX, IHC4 and Mammostrat
BRAF Testing	**TA 269:** Vemurafenib for treating locally advanced or metastatic BRAF V600 mutation-positive malignant melanoma **TA 321:** Dabrafenib for treating unresectable or metastatic BRAF V600 mutation-positive melanoma
KIT Testing	**TA 86:** Imatinib for the treatment of unresectable and/or metastatic gastro-intestinal stromal tumours (updated) **TA326:** Imatinib for the adjuvant treatment of gastrointestinal stromal tumours
ALK Testing (IHC)	**TA 296:** Crizotinib for previously treated non-small-cell lung cancer associated with an anaplastic lymphoma kinase fusion gene
ALK Testing (FISH)	**TA 296:** Crizotinib for previously treated non-small-cell lung cancer associated with an anaplastic lymphoma kinase fusion gene

These proposals have now been confirmed and the above arrangement is now in place for 2016/17.

The full Tariff consultation document can be found here:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/499594/2016-17_national_tariff_statutory_consultation.pdf

Questions and Answers

The following Questions and Answers have been developed to help explain what these new arrangements mean and how the funding of these and future molecular tests will practically take place within the NHS in England.

How have these six molecular diagnostics tests been commissioned by NHS England and how have contracts been put in place for 2016/17?

NHS England is the national commissioner of prescribed Specialised Services and is responsible for the commissioning and funding of these tests as part of its wider cancer commissioning responsibilities.

NHS England commissioners (through the NHS Regional and local commissioning teams) use the NHS Standard Contract to contract for patient services from each specialised hospital provider, which from April 2016 includes these molecular diagnostic tests.

The NHS Standard Contract includes a contract activity spreadsheet that sets out the expected level of activity to be delivered each month by the hospital provider – e.g. 200 outpatient appointments per specialty, 1000 A&E attendances etc. Under the NTPS a national Tariff (price) is set for many of these activities, (e.g. a first outpatient appointment for general surgery has a national tariff (price) of £144).

This month-by-month activity baseline enables a contract value to be assigned to the contract (activity x tariff). If for example, the baseline activity equates to £10M per month the contract has an overall value of £120M per year. To provide the hospital provider with cash flow the commissioner will agree to pay £10M per month. However, under the NTPS hospital providers are paid on the actual patient activity undertaken under the contractual agreement and the NTPS rules, not on the expected activity levels set out in the contract.

Therefore, in the above example the commissioner will pay the hospital provider an initial payment on 1st April of £10M. The hospital provider undertakes patient activity during April, and early in May will send an invoice (and the supporting patient level activity data) to the commissioner for the value of the actual patient activity undertaken in the month. This could, of course, be above or below the expected activity level in the contract activity spreadsheet – i.e. the hospital provider may have undertaken 214 first outpatient appointments, or only seen 967 A&E attendances. The commissioner and hospital provider validate the activity levels/value and reconcile the actual payment against the initial £10M payment on an ongoing basis.

It is important to note that the contract activity spreadsheet sets out the expected volumes of activity – it does not set a specific activity 'cap'.

In previous years under the NTPS the costs of providing these molecular tests was included within the larger HRG tariff payment for an individual patient and should not have been invoiced for separately by hospital providers. However, no specific technical guidance was issued on this point and locally some hospital providers were unsure of the level of reimbursement.

From April 2016 this position has been clarified. The costs of the six specific tests are NO LONGER included in the routine tariff payments and therefore NHS England will separately pay for these tests as part of the NHS Standard Contract held with a hospital provider.

To this end these six tests have been added to the list of 'High Cost Drugs, procedures and devices' – a list of items that are excluded from the tariff payment system. This provides clarity that the commissioning of these tests (and their funding) is through the inclusion of additional specific lines within the NHS Standard Contract between NHS England and the hospital provider.

The NHS England regional and local area commissioning teams have assumed responsibility for commissioning these tests from their local hospital providers and will have discussed with the hospital contracting team both the expected number of tests to be undertaken each month by the provider and agreed a 'local price' for each test for 2016/17. These discussions would have taken place during January to March 2016 and will now be included in hospital provider contracts for the 2016/17 financial year.

Will NHS England commissioners contract with individual pathology departments or the NHS hospital provider?

NHS England will contract directly with the hospital provider.

It is important to note that NHS England holds a contract with a hospital provider for patient services commissioned under the contract and as such agrees to fund the hospital provider for the costs of the

appropriate molecular tests undertaken for patients treated under that contract.

Under the contract, NHS England will therefore reimburse the contracted hospital provider for the costs of the molecular tests undertaken.

Where a hospital provider sends patient samples to a third party pathology unit, the hospital provider will need to put in place appropriate contractual/ invoicing arrangements for these services to be delivered. NHS England will reimburse the principal hospital provider for the patient activity delivered under the contract - NHS England will NOT be contracting or reimbursing third party pathology providers.

Therefore any hospital providers that are 'subcontracting' molecular testing to 'external' pathology units should have engaged with these units to ensure that they have in place an appropriate request and invoicing/payment contract/system to enable hospital clinicians to request tests and for the external pathology unit to invoice the principal hospital provider for the costs of the tests performed.

Is the number of molecular tests undertaken by a hospital provider set under the NHS Standard Contract?

No.

NHS England commissioners, as part of the routine contracting process, will have set out an initial activity level for each test expected to be provided within the overall contract with the hospital provider for patient services.

Although the inclusion of these six tests is new for 2016/17, NHS England commissioners already have an expectation of total testing volumes nationally, and have therefore, in discussion with the hospital provider, set the indicative activity levels. This need not specify a contract limit or cap.

However, note that NHS England and the hospital provider can quickly identify significant deviations from expected levels as these are tracked monthly through the normal contracting data sets.

Will a clinician need to request funding for an individual test request?

No.

Under the new process the contracting and reimbursement of a molecular test is included within the NHS Standard Contract - under which the hospital provider will be reimbursed the costs of the tests undertaken at the request of its' clinicians. As such, a clinician should not need to complete a 'funding request form' as they may have had to do previously for these tests.

Will NHS England and hospital providers put in place specific data recording systems to monitor the number of individual tests undertaken?

No – at least not for 2016/17.

At present, NHS England will use the routine contract monitoring systems in place with each hospital provider to monitor and pay for test activity. In the future NHS England may require providers to report activity through a national system – such as the BlueTeq system - but this has yet to be decided.

So is there a national price set for each molecular test?

No.

For 2016/17 NHS England has NOT set a specific national tariff (price) for each of the tests and therefore prices have been determined locally in negotiation with the individual hospital provider. However, there is one exception to this, for the Oncotype DX test, where the price has already been set nationally according to a confidential agreement with the test manufacturer.

Whilst this approach enables a pragmatic and sensible approach to payment for these tests for 2016/17, as a national commissioner NHS England will have oversight of any significant price variation between providers.

Is there some flexibility in the type of test delivered to achieve the test result?

NHS England commissioners were expected to have pragmatic discussions with hospital providers, and where appropriate agree some local flexibility if a provider wished to use a new test kit that is equally effective but cheaper, or for a newer test if that means speedier results or that tests can be delivered in a more efficient manner locally.

Will NHS England set Service Specifications for these use of these tests and will NHS England specify particular test kits to be used?

No – not for 2016/17.

However, funding for the tests is linked to specific NICE guidance for particular indications and treatments. Over time it may become clear that there are specific cost effective options which may lead to specific tests being favoured but any service specifications will be developed with clinical input.

Questions and Answers (continued)

Why does the National Tariff Payment System propose that these tests are only 'excluded' for three years? What does this mean?

This relates to the process by which the national tariff prices are set. In a nutshell each year hospital providers report, through the national reference cost data collection exercise, the actual costs of the patient activity undertaken in the previous year. The costs of activities on the 'High Cost list' are also captured through this collection. As such, as the use and costs of the activities – in this case the costs of the molecular tests – are captured they can be assessed and assigned within the existing tariff structures. Given the lags in the system, it is only after three years that the costs of the molecular tests will feed through into the associated treatment tariffs. Therefore, after three years, the molecular tests can be removed from the 'Excluded list' as the appropriate tariffs will by then include the costs of the tests.

Importantly, when this is done it will be explicit that the costs of the tests are then included within the routine tariff structures and a hospital provider can be assured that the appropriate reimbursement will continue to be made.

Where does EGFR Testing sit within this system?

EGFR testing for lung cancer, along with oestrogen (+/- progesterone) receptor status and HER2 testing for breast cancer, have been established tests within the NHS for a number of years. NHS England has clarified that the costs of these tests have been reported through the NHS reference cost exercise and so are now included in the wider tariff system. Therefore unlike the six specific tests identified here as being 'excluded' from the tariff (and paid for separately), hospitals are being reimbursed for EGFR tests through the HRG tariff system.

However, we are aware from the Cancer Strategy that many patients are not receiving this test. This could be because the reimbursement route has not been explicitly stated, causing local uncertainty that the costs of EGFR tests are being reimbursed in this way.

If this is the case locally we would urge you in the first instance to contact your hospital's finance / contracting team who can, if necessary, seek further clarification through NHS England Regional Commissioning Managers. We will continue to monitor this situation.

Looking to the future

How will new tests be introduced into the system?

The recently published '*Achieving World Class Cancer Outcomes: Taking the strategy forward*' noted that *'Going forward, any new test linked to use of a new cancer drug included by NICE within its technology appraisal, will be mandated for use across the system when the drug is recommended by NICE*'. This approach extends to tests included as part of future NHS England approved clinical commissioning policies.

Reimbursement for the costs of new tests approved as part of a NICE TA or an NHS England approved commissioning policy may similarly be commissioned and funded through the 'exclusion from tariff route' as described here, although alternative funding approaches may also be considered, depending upon the nature of the test.

What about the bigger picture?

With the ongoing implementation of '*Achieving World-Class Cancer Outcomes: a strategy for England*', the development of the NHS England Personalised Medicines Strategy and the creation of new care models stemming from the Five Year Forward View, the focus is on continuous improvement – both on improving patient outcomes and increasing the efficiency of how NHS services are delivered. As such the provision (and therefore the contracting and payment mechanisms) for the increasing range of molecular and related tests will continue to evolve. We will continue to work with NHS England to support the implementation of all the recommendations set out in the Cancer Strategy, including the move towards multiplex panel testing.

This new contracting mechanism brought in for 2016/17 is however, a significant first step.

Further information within the NHS

For further information, in the first instance please contact your hospital's finance / contracting team. They will be in regular contract with their lead NHS England commissioner within the Regional Team and will be able to clarify any specific issues you may have.

For further information on BIVDA, CRUK and the ABPI please contact:

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