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18 January 2012

Gateway ref: 17067

Dear colleague

Cystic fibrosis guidance

In the 2012-13 Payment by Results road test package we said that guidance on cystic fibrosis would follow. This is set out in Annex A to this letter, and will be incorporated into the final version of the PbR guidance to be published in February 2012. Also attached are the tariffs for 2012-13 at Annex B, and a worked example of the banding at Annex C.

Background

You will know that there has been significant work undertaken over the past four years on the development of a CF year of care tariff, and we would like to thank commissioners, providers and the Cystic Fibrosis Trust for all of their input.

Proposal for 2012-13

As a result the plan for implementing tariffs for 2012-13 will be:

a. Tariffs, based on the Price Waterhouse Cooper costing published in the 2012-13 sense check, for each of the bandings are now available. The tariffs will be **exclusive** of the costs of the following drugs: Colistimethate sodium, Tobramycin, Dornase alfa and Aztreonam Lysine. These have been adjusted to remove MFF and to adjust for pay and price inflation and efficiency requirements.

b. The tariffs will be paid to specialist CF centres only.

c. The new tariffs will be phased in over two years with the tariff mandatory in 2013-14. The year of care currency is mandatory as the basis on which CF services are commissioned in 2012-13.

d. The tariffs will be updated for 2013-14 (using new cost data when available). 2011-12 reference costs will be collected in Summer 2012 and published in Autumn 2012. These will be

collected on the basis of the new cystic fibrosis currencies. We also wish to revisit the 2010-11 reference costs and work with providers to try and collect these on the basis of the new CF currencies. All of this information will be used in conjunction with the PwC work to inform the 2013-14 tariff.

e. The named high cost drugs are excluded from the tariff and will be paid for locally. Prescribing of these high cost drugs will be governed by a new national commissioning policy. The responsibility for determining eligibility for the named drugs, in accordance with the national commissioning policy, will be retained by the specialist centre.

f. Commissioners and providers will need to agree local transition plans to enable movement to full tariff from April 2013. Transition plans will take account of how shared/network care for children will be funded in 2012-13 and the requirement for all CF specialist centres to implement the proposed mandatory tariff for 2013-14. As part of these transition plans, providers and commissioners will need to agree an impact assessment comparing current funding with tariff funding.

g. CF will be commissioned by SCGs from April 2012. There will be a national service specification which will require specialised CF services to meet a series of contract requirements of care and quality measures. Transition plans will take account of how and by when these requirements will be met.

h. From April 2013, the only funding available for shared/network care for children will be as a proportion of tariff received by the specialist CF centre with which care is shared. During 2012-13 work will be undertaken to ensure the development of local service specifications and service level agreements to address the provision and funding of shared/network care for children.

The broad principles for PbR set out in the Code of Conduct also apply to CF services.

So, there remain several important tasks that need to be undertaken over the next year before the tariff for CF becomes mandatory in April 2013. We look forward to working with you to complete them.

Yours faithfully

Martin Campbell
Deputy Director, NHS Finance

Cystic fibrosis

Currency

1. The cystic fibrosis (CF) currency is a complexity-adjusted yearly banding system with seven bands of increasing complexity. There is no distinction between adults and children.

Banding

2. Bandings are derived from clinical information including cystic fibrosis complications and drug requirements. The bands range from band one, for the patients with the mildest care requirements (involving outpatient treatment two to three times a year and oral medication) to band five, for patients at the end stage of their illness (requiring intravenous antibiotics in excess of 113 days a year with optimum home or hospital support).

3. The non-mandatory tariff is designed to allow specialist CF multidisciplinary teams to direct care in a seamless, patient centred manner, removing any perverse incentives to hospitalise patients who can be well managed in the community and in their home. Furthermore, it will allow early intervention, as per international guidelines, to prevent disease progression for example through the use of anti-pseudomonas, inhaled/nebulised antibiotics and mucolytic therapy.

4. The CF banding matrix identifies the characteristics which will lead a patient to be classified into a particular band.

5. Patients are allocated to a band by extracting data from the Cystic Fibrosis Trust national database, the UK CF Registry and feeding it into a template that produces the banding. The banding matrix and an example of how to use it is provided at Annex C.

6. Banding will be issued each February using the data input to the UK CF Registry. This information is based on a calendar year's data and will be used both to fine tune the planning assumptions made for the next financial year and for initial planning purposes for the following year.

7. Banding information, based on the 2010 calendar year, was issued in 2011. This information should be used for planning purposes for the financial year 2012-13. In February 2012 updated banding information based on 2011 calendar year will be issued. Commissioners will use this information to finalise their planning assumptions for 2012-13. The bands issued in February 2012 will be the final bands for all patients for 2012-13 and will be used for contracting purposes. There will be no movement of patients between bands during any one financial year.

Patient numbers

8. There are likely to be changes in the number of patients in each band in the cohort of CF patients at any one centre. This will be due to increases and decreases in patient numbers due to births, transition from children's to adult services, natural patient movement from one area to another, transplantation and deaths. Whilst the tariff is payment for a year of care, in reality payments are most likely to be made in twelfths as part of contract payments. Changes in patient numbers will be addressed as follows:

   (a) New births. Payment is calculated from the beginning of the month in which the patient is born. New births will be banded as 2A, which recognises the additional costs associated with diagnosis, care and treatment of a new patient. These patients will revert to the band issued through the process described above when the bandings are revised for the following year.

   (b) Transition to an adult service or to another specialist CF centre. Clinical transition or transfer to another centre may take place over a period of time. For the purposes of payment the two centres must agree a date at which responsibility of care will transfer. The date on which responsibility ceases must always be the last day of a calendar month and the date on which the new centre assumes responsibility for care must always be the first day of the new calendar month. These finalised dates will be used by commissioners to cease payment to the original centre and commence payment to the receiving centre.

   In some circumstances, such as university students or patients needing care whilst on holiday, there may not be a formal transfer of care as an individual may not wish or need to have their care transferred to a new centre. Should treatment be required away from the centre responsible for their care, the responsible centre will be expected to pay for that care. This will be a provider to provider transaction.

   (c) Deaths. Payments for patients who die will cease at the end of the month in which they die.

   (d) Transplants. Heart and heart/lung, lung and liver transplants are commissioned by the Advisory Group for National Specialised Services (AGNSS). Payment of the non-mandatory CF tariff for patients receiving a transplant will cease at the end of the month in which they receive their transplant. Funding for any continuing care from a CF specialist centre following a transplant will need to be determined locally.

Information on patient number variations

9. Each provider will be responsible for informing commissioners of changes in patient numbers due to new births, transition and transfers, deaths and transplants so as to enable commissioners to reconcile payments on a regular basis. The UK CF Registry will send monthly reports to commissioners to enable them to verify the changes reported by providers.

10. It will be incumbent upon providers to agree upon payment for any patient who has not formally transferred responsibility for their care to another centre.

What is included in the non-mandatory tariffs?

11. The bandings cover all treatment **directly** related to cystic fibrosis for a patient during the financial year. This includes:

    (a) Admitted patient care and outpatient attendances (whether delivered in a specialist centre or under shared network care arrangements).
    (b) Home care support, including home intravenous antibiotics supervised by the CF service, home visits by the multidisciplinary team to monitor a patient's condition, eg management of totally implantable venous access devices (TIVADs), collection of mid-course aminoglycoside blood levels and general support for patient and carers.
    (c) Intravenous antibiotics provided during in-patient spells
    (d) Annual review investigations

12. Any episode directly related to CF specific care (admitted patient care or outpatient activity) will not attract additional activity based payments as these are included in the annual banded tariff, eg admitted for treatment of exacerbation of chest infection, admitted for medical treatment of CF distal intestinal obstruction syndrome, admitted with a new diagnosis of CF-related diabetes to establish a new insulin regimen. To help identify cystic fibrosis activity, TFCs for adult cystic fibrosis (TFC 343) and paediatric cystic fibrosis (TFC 264) were introduced in 2011. A primary diagnosis of cystic fibrosis may also be a useful way to identify CF specific care.

What is excluded from the non-mandatory tariffs?

13. The following are explicitly not included in the non-mandatory CF tariff:

    (a) High cost CF specific **inhaled/nebulised** drugs: Colistimethate sodium, Tobramycin, Dornase alfa and Aztreonam Lysine.
    (b) Insertion of gastrostomy devices (PEG) and insertion of totally implantable venous access devices (TIVADs) are not included in the annual banded tariff. Surgical procedures should be reimbursed via the relevant HRG tariff.
    (c) Neonates admitted with meconium ileus who are subsequently identified to have cystic fibrosis should not be subject to the CF

tariff until they have been discharged after their initial surgical procedure. This should be reimbursed via the relevant HRG tariff. Subsequent annual banding should not include the period they spent as an admitted patient receiving their initial surgical management.

14. CF patients may require medical input from other specialties for non-CF specific care. The costs relating to non-CF specific care are not included in the annual banded tariff. These episodes of care will be covered by tariffs assigned to the relevant HRG or TFC, eg obstetric care for a female patient with CF, ENT outpatient review for nasal polyps and ENT surgery for removal of nasal polyps.

Drugs

15. Prescription of the high cost drugs Colistimethate sodium, Tobramycin, Dornase alfa and Aztreonam Lysine that are used in the treatment of CF patients will be initiated by the specialist CF centre. Continuation of the prescription, whether from the specialist CF centre or the GP, will be by local arrangement.

16. Funding of Colistimethate sodium, Tobramycin, Dornase alfa and Aztreonam Lysine will be governed by national commissioning policies. Commissioners will need to ensure that the arrangements are clear with each specialist CF centre for the continuing prescription of these drugs to enable the appropriate funding flow.

17. Where continuation of prescribing is left with the specialist CF centre, the use of home delivery systems should be encouraged.

18. GPs will continue to prescribe and fund all other chronic specific medication, for example long-term oral antibiotics, pancreatic enzyme replacement therapy and vitamin supplements.

19. There are a number of high cost antifungal treatments excluded from PbR, which are therefore not included in the CF tariff.

20. Costs associated with long-term nutritional supplementation via gastrostomy or nasogastric tube feeding are not included in the annual banded tariff and will remain within the primary care budget.

21. When looking at the cost and payment of any new high cost drugs approved for use in CF by NICE and/or commissioners, it may be appropriate for commissioners and providers to consider the use of innovation payments, to address the cost and payment of these drugs.

Tariff principles and service designation

22. CF care will be provided on the basis of the following principles:

    (a) All patients will be registered with a designated CF specialist centre which will be responsible for all care directly related to the patient's CF.

(b) Designated CF centres will be responsible for ensuring that the data of all the patients for whom they are responsible are entered on the national CF database, the UK CF Registry. Patients/carers who do not wish their data to be entered on the UK CF Registry must express this wish in writing to their clinician at the specialist centre.
(c) All CF treatment and care for both adults and children will be delivered by clearly designated providers.
(d) For adults all the treatment and care will be the responsibility of the specialist centre with no shared care arrangements in place.
(e) For children, the treatment centre will initiate all treatments with treatment and care being delivered in either a centre or designated district general hospitals in the framework of a shared care network. Inter Trust service level agreements will be in place to support these arrangements.
(f) The providers of CF services – centres and shared care units – will need to comply with the relevant service specification and meet the service standards.
(g) Access to and eligibility for CF specialist drugs will be determined by national commissioning policy.
(h) The relevant CF centre will be responsible for initiating <u>all</u> current CF specialist drugs.

23. Using these principles, payment of CF tariffs will only be made to designated specialised CF centres. The formal process of designating treatment centres will take some time. For the purposes of the 2012-13 tariff, designated centres will be those which meet the following criteria:

(a) The provider trust will have agreed with the commissioner of the service that it will be a specialist centre for CF.
(b) The centre will have accepted the national service specification(s) for the provision of cystic fibrosis treatment for children and/or adults (as appropriate) and will have incorporated the specification(s) into the 2012-13 contract.
(c) The centre will either already meet the requirements contained within the service specification or will have a plan agreed with the commissioner of the service to meet those requirements by April 2014.
(d) The centre will meet the requirements for data entry into the UK CF Registry as detailed in the UK CF Registry operating procedure from 1 April 2012.

Shared / network care

24. Whilst shared care arrangements may be more appropriate for children with CF it is important to distinguish between shared care and outreach care.

25. Shared/network care is a recognised model for paediatric care. Shared/network care clinics take place in district general hospitals close to the homes of people with CF, where care is provided in partnership with the responsible Specialist CF Centre. This model of care must

provide care that is of equal quality and access as full Specialist Centre care.

26. Outreach care is defined as care provided by a Specialist Centre care team who travel to a local district general hospital. Typically, but not exclusively, this may occur in geographically challenging areas so as to minimise difficult journeys that people with CF have to make. In all cases CF tariffs will only be paid to designated Specialist CF Centres.

Payment for shared/network care

27. Further work needs to be done to standardise share care and network care, including understanding how shared care is currently being funded. In the meantime payments will be subject to local arrangements.

Details of the non-mandatory tariffs

28. The non-mandatory tariffs for 2012-13 are included in the *tariff information spreadsheet*. The tariffs for bands 1A and 2 are the same, reflecting the similar costs of service provision. For 2013-2014 it is proposed to merge these two bands.

29. As cystic fibrosis is in itself a specialised service the non-mandatory tariffs are not eligible for any top-up relating to specialised services.

CF proposed tariffs 2012-13 with high cost drugs excluded and adjusted for staff and cost changes and efficiency requirements

1	£5,210
1a	£7,707
2	£7,707
2a	£12,457
3	£19,067
4	£34,388
5	£41,458

Annex C - Example for cystic fibrosis banding

Step one: define the value for each criteria

The values for Patient A are:

FEV_1% predicted lung function	75%
Maximum number of total days of IV antibiotics	12
Nebulised antibiotics (*Pseudomonas* infection)	Yes
Long-term (>3 months) nebulised antibiotics OR DNase	No
Long-term (>3 months) nebulised antibiotics AND DNase	No
Maximum numbers of days in hospital	7
Nasogastric feeds	Yes
Gastrostomy	No
CF Related Diabetes OR ABPA w/o other complications	Yes
CF Related Diabetes AND ABPA	No
Massive Haemoptysis OR Pneumothorax	No
CF Related Diabetes AND Gastrostomy	No
Non Tuberculous mycobacterium treated or difficult to treat infections (MRSA)	No

Step two: determine the band for each criteria using the CF banding matrix:

Banding definitions		Band						
		1	1A	2	2A	3	4	5
Therapies	Maximum number of total days of IV antibiotics	0	14	28	56	84	112	≥113
	Nebulised antibiotics (*Pseudomonas* infection)		Yes					
	Long-term (>3 months) nebulised antibiotics or DNase			Yes				
	Long-term (>3 months) nebulised antibiotics and DNase				Yes			
Hospitalisations	Maximum numbers of days in hospital	0	7	14	14	57	112	≥113
Supplemental feeding	Nasogastric feeds				Yes			
	Gastrostomy					Yes		
Complications	CF Related Diabetes or ABPA w/o other complications				Yes			
	CF Related Diabetes and ABPA					Yes and (FEV_1 ≥60%)	Yes and (FEV_1 <60%)	
	Massive Haemoptysis or Pneumothorax					Yes and (FEV_1 ≥60%)	Yes and (FEV_1 <60%)	
	CF Related Diabetes and Gastrostomy					Yes and (FEV_1 ≥60%)	Yes and (FEV_1 <60%)	
	Non Tuberculous mycobacterium treated or difficult to treat infections (eg MRSA or Cepacia) requiring other nebulised antibiotics eg Meropenem, Cayston , Vancomycin.					Yes		

It is to be expected that the criteria will fit multiple bands. In our example, patient A is eligible for bands 1, 1A and 2A.

Step three: allocate the patient to their highest band

In our example, patient A is allocated to band 2A. This process is repeated for each patient. The process is automated by extracting data from the Cystic Fibrosis Registry and feeding it into a template that produces the banding.