

## Integrated Impact Assessment Report for Clinical Commissioning Policies

<b>Policy Reference Number</b>	1621		
<b>Policy Title</b>	Inhaled therapy levofloxacin Proposal <b>for routine commission</b> (ref A3.1)		
<b>Lead Commissioner</b>	Kathy Blacker	<b>Clinical Lead</b>	Thomas Daniels
<b>Finance Lead</b>	Jacqui Low	<b>Analytical Lead</b>	Jacqui Low

### Integrated Impact Assessment – Index

Section A – Activity	Section B - Service	Section C – Finance
A1 Current Patient Population & Demography / Growth	B1 Service Organisation	C1 Tariff
A2 Future Patient Population & Demography	B2 Geography & Access	C2 Average Cost per Patient
A3 Activity	B3 Implementation	C3 Overall Cost Impact of this Policy to NHS England
A4 Existing Patient Pathway	B4 Collaborative Commissioning	C4 Overall cost impact of this policy to the NHS as a whole
A5 Comparator (next best alternative treatment) Patient Pathway		C5 Funding
A6 New Patient Pathway		C6 Financial Risks Associated with Implementing this Policy
A7 Treatment Setting		C7 Value for Money
A8 Coding		C8 Cost Profile
A9 Monitoring		

### About this Impact Assessment: instructions for completion and explanatory notes

- Each section is divided into themes.
- Each theme sets out a number of questions.
- All questions are answered by selecting a drop down option or including free text.
- Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text.
- Data in this document is either drawn from one of the relevant policy documents or a source for the information is provided.
- Where assumptions are included where data is not available, this is specified.

**Section A - Activity Impact**

**A1 Current Patient Population & Demography / Growth**

<p>A1.1 Prevalence of the disease/condition.</p>	<p>In 2015 the UK National Registry reported 8,823 people with CF aged 18 years and over in England. Of these there are 4,450 with chronic Pa  <i>Source:</i></p>								
<p>A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.</p>	<p>200  <i>Source:</i> UK CF National Registry</p>								
<p>A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.</p>	<p><b><u>Adults</u></b>          Please specify          This policy is for 18 years old and over</p>								
<p>A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria</p>	<p>18 and over, with an estimated <i>median age of 24-27</i>  <i>Source: UK CF National Registry</i></p>								
<p>A1.5 How is the population currently distributed geographically?</p>	<p><b><u>Evenly</u></b>          If unevenly, estimate regional distribution by %:</p> <table border="1" data-bbox="1088 1110 1599 1329"> <tr> <td>North</td> <td>enter %</td> </tr> <tr> <td>Midlands &amp; East</td> <td>enter %</td> </tr> <tr> <td>London</td> <td>enter %</td> </tr> <tr> <td>South</td> <td>enter %</td> </tr> </table> <p><i>Source: Policy Proposition section 6</i></p>	North	enter %	Midlands & East	enter %	London	enter %	South	enter %
North	enter %								
Midlands & East	enter %								
London	enter %								
South	enter %								

	Please specify NCDR
--	------------------------

**A2 Future Patient Population & Demography**

A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new policy) in 2, 5, and 10 years?	<b><u>Increasing</u></b> If other, incidence is stable yet prevalence is increasing due to increased survival <i>Source:</i>
---	--

A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	<b><u>No</u></b> <i>Source:</i>
---	------------------------------------

A2.3 Expected net increase or decrease in the number of patients who will be eligible for treatment, according to the proposed policy commissioning criteria, per year in years 2-5 and 10?	YR2 +/-	100
	YR3 +/-	100
	YR4 +/-	100
	YR5 +/-	100
	YR10 +/-	96
<i>Source: Policy Proposition section 6/ other</i>		

**A3 Activity**

A3.1 What is the purpose of new policy?	<b><u>Revise existing policy (expand or restrict an existing treatment threshold / Add an additional line of treatment / stage of treatment</u></b>
---	---

	Please specify The purpose of the new policy is to provide an alternate anti-bacterial therapy to prevent respiratory deterioration
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	200 <i>Source:</i> UK CF National Registry
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	200 <i>Source:</i> UK CF National Registry
A3.4 What is the estimated annual activity associated with the next best alternative comparator pathway for the eligible population? If the only alternative is the existing pathway, please state 'not applicable' and move to A4.	Not applicable
<b>A4 Existing Patient Pathway</b>	
A4.1 <b>Existing pathway:</b> Describe the relevant currently routinely commissioned: <ul style="list-style-type: none"> <li>• Treatment or intervention</li> <li>• Patient pathway</li> <li>• Eligibility and/or uptake estimates.</li> </ul>	Preventing chronic infection with <i>Pseudomonas aeruginosa</i> is a key element in increasing survival in patients with CF. Patients are treated with the following inhaled treatments which are routinely funded for: Tobramycin, Colistimethate sodium, Aztreonam lysine. Patients receive first line, a single therapy and this is usually followed by alternative therapies or combination therapies given one month on and one month off  <i>Source:</i> NHS England Clinical Commissioning Policy: Inhaled Therapy for Adults and Children with Cystic Fibrosis Reference A01/P/b (2015).

<p>A4.2. What are the current treatment access and stopping criteria?</p>	<p>Treatment covered by NHS policy and stopping criteria are failure of clinical efficacy, Lung transplantation, Development of intolerance or Death  <i>Source:</i> NHS England Clinical Commissioning Policy: Inhaled Therapy for Adults and Children with Cystic Fibrosis Reference A01/P/b (2015)</p>
<p>A4.3 What percentage of the total eligible population is expected to:</p> <ul style="list-style-type: none"> <li>a) Be clinically assessed for treatment</li> <li>b) Be considered to meet an exclusion criteria following assessment</li> <li>c) Choose to initiate treatment</li> <li>d) Comply with treatment</li> <li>e) Complete treatment?</li> </ul>	<p>If not known, please specify</p> <ul style="list-style-type: none"> <li>a) 100%</li> <li>b) 0</li> <li>c) 100%</li> <li>d) 100%</li> <li>e) 100%</li> </ul>
<p><b>A5 Comparator (next best alternative treatment) Patient Pathway</b>  (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)</p>	
<p><b>A5.1 Next best comparator:</b>  Is there another 'next best' alternative treatment which is a relevant comparator?  <i>If yes, describe relevant</i></p> <ul style="list-style-type: none"> <li>• <i>Treatment or intervention</i></li> <li>• <i>Patient pathway</i></li> <li>• <i>Actual or estimated eligibility and uptake</i></li> </ul>	<p><b><u>No</u></b></p>
<p>A5.2 What percentage of the total eligible population is estimated to:</p> <ul style="list-style-type: none"> <li>a) Be clinically assessed for treatment</li> </ul>	<p>Total estimated eligible</p> <ul style="list-style-type: none"> <li>a) enter %</li> </ul>

<ul style="list-style-type: none"> <li>b) Be considered to meet an exclusion criteria following assessment</li> <li>c) Choose to initiate treatment</li> <li>d) Comply with treatment</li> <li>e) Complete treatment?</li> </ul>	<ul style="list-style-type: none"> <li>b) 0</li> <li>c) enter %</li> <li>d) enter %</li> <li>e) enter %</li> </ul>
<b>A6 New Patient Pathway</b>	
<p>A6.1 What percentage of the total eligible population is expected to:</p> <ul style="list-style-type: none"> <li>a) Be clinically assessed for treatment</li> <li>b) Be considered to meet an exclusion criteria following assessment</li> <li>c) Choose to initiate treatment</li> <li>d) Comply with treatment</li> <li>e) Complete treatment?</li> </ul>	<p>If not known, please specify <a href="#">Click here to enter text.</a></p> <ul style="list-style-type: none"> <li>a) 100%</li> <li>b) 0</li> <li>c) 100%</li> <li>d) 100%</li> <li>e) 100%</li> </ul> <p><i>Source:</i> There is published evidence that compliance with treatment is around 36%. However it is difficult to accurately model the impact of this from missing the occasional dose to not using at all. We can anticipate that compliance with treatment will rise as a result of the current NIHR study on patient activation, which NHS England are supporting through a CQUIN. We have therefore modelled usage at 100% for the purpose of this impact assessment.</p>
<p>A6.2 Specify the nature and duration of the proposed new treatment or intervention.</p>	<p><b><u>Life long</u></b></p> <p>For time limited treatments, specify frequency and/or duration.</p> <p>6 cycles of 28 days on 28 days off</p> <p><i>Source:</i> Policy Proposition Section 7 in line with NHS England Clinical Commissioning Policy: Inhaled Therapy for Adults and Children with Cystic Fibrosis Reference A01/P/b (2015).</p>

## A7 Treatment Setting

A7.1 How is this treatment delivered to the patient?

*Select all that apply:*

Emergency/Urgent care attendance	<input type="checkbox"/>
Acute Trust: inpatient	<input checked="" type="checkbox"/>
Acute Trust: day patient	<input type="checkbox"/>
Acute Trust: outpatient	<input checked="" type="checkbox"/>
Mental Health provider: inpatient	<input type="checkbox"/>
Mental Health provider: outpatient	<input type="checkbox"/>
Community setting	<input type="checkbox"/>
Homecare	<input checked="" type="checkbox"/>
Other	<input type="checkbox"/>

A7.2 What is the current number of contracted providers for the eligible population by region?

NORTH	6
MIDLANDS & EAST	6
LONDON	4
SOUTH	7



A7.3 Does the proposition require a change of delivery setting or capacity requirements?

**No**

Source: Policy Proposition Section 7

## A8 Coding

A8.1 Specify the datasets used to record the new patient pathway activity.

\*expected to be populated for all commissioned activity

Select all that apply:

Aggregate Contract Monitoring *	<input checked="" type="checkbox"/>
Patient level contract monitoring	<input checked="" type="checkbox"/>
Patient level drugs dataset	<input checked="" type="checkbox"/>
Patient level devices dataset	<input type="checkbox"/>
Devices supply chain reconciliation dataset	<input type="checkbox"/>
Secondary Usage Service (SUS+)	<input checked="" type="checkbox"/>
Mental Health Services DataSet (MHSDS)	<input type="checkbox"/>
National Return**	<input type="checkbox"/>
Clinical Database**	<input checked="" type="checkbox"/>
Other**	<input type="checkbox"/>

\*\*If National Return, Clinical database or other selected, please specify:  
UK CF National Registry

A8.2 Specify how the activity related to the new patient pathway will be identified.

Select all that apply:

	<table border="1"> <tr> <td data-bbox="1079 97 1751 156">OPCS v4.8</td> <td data-bbox="1751 97 1839 156"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1079 156 1751 215">ICD10</td> <td data-bbox="1751 156 1839 215"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1079 215 1751 274">Treatment function code</td> <td data-bbox="1751 215 1839 274"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1079 274 1751 333">Main Speciality code</td> <td data-bbox="1751 274 1839 333"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1079 333 1751 392">HRG</td> <td data-bbox="1751 333 1839 392"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1079 392 1751 451">SNOMED</td> <td data-bbox="1751 392 1839 451"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1079 451 1751 539">Clinical coding / terming methodology used by clinical profession</td> <td data-bbox="1751 451 1839 539"><input type="checkbox"/></td> </tr> </table> <p data-bbox="1079 555 1982 587">Drug will be mapped to the Adult CF Service Code: NCBPS10z</p>	OPCS v4.8	<input type="checkbox"/>	ICD10	<input type="checkbox"/>	Treatment function code	<input checked="" type="checkbox"/>	Main Speciality code	<input checked="" type="checkbox"/>	HRG	<input type="checkbox"/>	SNOMED	<input checked="" type="checkbox"/>	Clinical coding / terming methodology used by clinical profession	<input type="checkbox"/>
OPCS v4.8	<input type="checkbox"/>														
ICD10	<input type="checkbox"/>														
Treatment function code	<input checked="" type="checkbox"/>														
Main Speciality code	<input checked="" type="checkbox"/>														
HRG	<input type="checkbox"/>														
SNOMED	<input checked="" type="checkbox"/>														
Clinical coding / terming methodology used by clinical profession	<input type="checkbox"/>														
<p data-bbox="91 651 629 683"><b>A8.3 Identification Rules for Drugs:</b></p> <p data-bbox="91 699 517 730">How are drug costs captured?</p>	<p data-bbox="1079 651 2049 683"><b><u>Already specified in current NHS England Drugs List document</u></b></p> <p data-bbox="1079 699 2101 762">If the drug has already been specified in the current NHS England Drug List please specify drug name and drug indication:</p> <p data-bbox="1079 778 2056 810">Levofloxacin (inhaled), Cystic Fibrosis – Not routinely commissioned</p> <p data-bbox="1079 826 2101 922">If the drug has NOT already been specified in the current NHS England Drug List please give details of action required and confirm that this has been discussed with the pharmacy lead:</p> <p data-bbox="1079 938 1624 970">Discussed with NPOC pharmacy lead</p>														
<p data-bbox="91 1034 658 1066"><b>A8.4 Identification Rules for Devices:</b></p> <p data-bbox="91 1082 551 1114">How are device costs captured?</p>	<p data-bbox="1079 1034 1308 1066"><b><u>Not applicable</u></b></p> <p data-bbox="1079 1082 2116 1177">If the device is covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance).</p> <p data-bbox="1079 1241 2056 1337">If the device is not excluded from Tariff <b>nor</b> covered within existing National or Local prices please specify details of action required and confirm that this has been discussed with the HCTED team.</p>														

**A8.5 Identification Rules for Activity:**

How are activity costs captured?

**Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool)**

If activity costs are already captured please specify the specialised service code and description (eg NCBPS01C Chemotherapy).

NCBPS10z

If activity costs are already captured please specify whether this service needs a separate code. **No**

If the activity is captured but the service line needs amendment please specify whether the proposed amendments have been documented and agreed with the Identification Rules team.

Not Applicable

If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. **No**

**A9 Monitoring**

**A9.1 Contracts**

Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.

**None**

**A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model)**

For treatments which are tariff excluded drugs or devices not covered by the Zero Cost Model, specify the pharmacy or device monitoring required, for example reporting or use of prior approval systems.

*Select all that apply:*

Drugs or Device MDS	<input checked="" type="checkbox"/>
Blueteq	<input checked="" type="checkbox"/>
Other prior approval	<input type="checkbox"/>

<p><b>A9.3 Business intelligence</b> Is there potential for duplicate reporting?</p>	<p><b><u>No</u></b> If yes, please specify mitigation:</p>
<p><b>A9.4 Contract monitoring</b> Is this part of routine contract monitoring?</p>	<p><b><u>Yes</u></b> If yes, please specify contract monitoring requirement: ACM, Blueteq and Drug MDS</p>
<p><b>A9.5 Dashboard reporting</b> Specify whether a dashboard exists for the proposed intervention?</p>	<p><b><u>No</u></b> If yes, specify how routine performance monitoring data will be used for dashboard reporting.  If no, will one be developed? No</p>
<p><b>A9.6 NICE reporting</b> Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy?</p>	<p><b><u>No</u></b> If yes, specify how performance monitoring data will be used for this purpose. no</p>
<p><b>Section B - Service Impact</b></p>	
<p><b>B1 Service Organisation</b></p>	
<p><b>B1.1</b> Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc)</p>	<p>They are commissioned through specialised centres <i>Source:</i> Policy Proposition Section 7 in line with NHS England Clinical Commissioning Policy: Inhaled Therapy for Adults and Children with Cystic Fibrosis Reference A01/P/b (2015).</p>

B1.2 Will the proposition change the way the commissioned service is organised?	<b>No</b>								
B1.3 Will the proposition require a new approach to the organisation of care?	<b><u>No change to delivery of care</u></b>								
<b>B2 Geography &amp; Access</b>									
B2.1 Where do current referrals come from?	<p>Select all that apply:</p> <table border="1"> <tr> <td>GP</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Secondary care</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Tertiary care</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Other</td> <td><input type="checkbox"/></td> </tr> </table>	GP	<input type="checkbox"/>	Secondary care	<input checked="" type="checkbox"/>	Tertiary care	<input checked="" type="checkbox"/>	Other	<input type="checkbox"/>
GP	<input type="checkbox"/>								
Secondary care	<input checked="" type="checkbox"/>								
Tertiary care	<input checked="" type="checkbox"/>								
Other	<input type="checkbox"/>								
B2.2 What impact will the new policy have on the sources of referral?	<b><u>No impact</u></b>								
B2.3 Is the new policy likely to improve equity of access?	<b><u>No impact</u></b> <i>Source: Equalities Impact Assessment</i>								
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	<b><u>Increase</u></b> Please specify: Improve outcomes <i>Source: Equalities Impact Assessment</i>								

<b>B3 Implementation</b>	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	<b><u>Contract action</u></b> Please specify: 28 days' notice of use of prior notification for Blueteq will be required
B3.2 <b>Time to implementation:</b> Is a lead-in time required prior to implementation?	<b><u>No - go to B3.4</u></b> If yes, specify the likely time to implementation: Enter text
B3.3 <b>Time to implementation:</b> If lead-in time is required prior to implementation, will an interim plan for implementation be required?	Choose an item. If yes, outline the plan: Click here to enter text.
B3.4 Is a change in provider physical infrastructure required?	<b><u>No</u></b> Please specify: Click here to enter text.
B3.5 Is a change in provider staffing required?	<b><u>No</u></b> Please specify: Click here to enter text.
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	<b><u>No</u></b> Please specify: Click here to enter text.
B3.7 Are there changes in the support services that need to be in place?	<b><u>No</u></b> Please specify:

	Click here to enter text.																								
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	<p><b>No</b> Please specify: Click here to enter text.</p>																								
B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and estimated number of providers required in each region	<p><b>No change</b> <i>Please complete table:</i></p> <table border="1" data-bbox="1088 464 2013 908"> <thead> <tr> <th>Region</th> <th>Current no. of providers</th> <th>Future State expected range</th> <th>Provisional or confirmed</th> </tr> </thead> <tbody> <tr> <td>North</td> <td>6</td> <td>6</td> <td><u>C</u></td> </tr> <tr> <td>Midlands &amp; East</td> <td>6</td> <td>6</td> <td><u>C</u></td> </tr> <tr> <td>London</td> <td>4</td> <td>4</td> <td><u>C</u></td> </tr> <tr> <td>South</td> <td>7</td> <td>7</td> <td><u>C</u></td> </tr> <tr> <td>Total</td> <td>23</td> <td>23</td> <td><u>C</u></td> </tr> </tbody> </table> <p>Please specify: Click here to enter text.</p>	Region	Current no. of providers	Future State expected range	Provisional or confirmed	North	6	6	<u>C</u>	Midlands & East	6	6	<u>C</u>	London	4	4	<u>C</u>	South	7	7	<u>C</u>	Total	23	23	<u>C</u>
Region	Current no. of providers	Future State expected range	Provisional or confirmed																						
North	6	6	<u>C</u>																						
Midlands & East	6	6	<u>C</u>																						
London	4	4	<u>C</u>																						
South	7	7	<u>C</u>																						
Total	23	23	<u>C</u>																						
B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.	<p><i>Select all that apply:</i></p> <table border="1" data-bbox="1088 1102 1998 1370"> <tbody> <tr> <td>Publication and notification of new policy</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Market intervention required</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Competitive selection process to secure increase or decrease provider configuration</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Price-based selection process to maximise cost</td> <td><input type="checkbox"/></td> </tr> </tbody> </table>	Publication and notification of new policy	<input checked="" type="checkbox"/>	Market intervention required	<input type="checkbox"/>	Competitive selection process to secure increase or decrease provider configuration	<input type="checkbox"/>	Price-based selection process to maximise cost	<input type="checkbox"/>																
Publication and notification of new policy	<input checked="" type="checkbox"/>																								
Market intervention required	<input type="checkbox"/>																								
Competitive selection process to secure increase or decrease provider configuration	<input type="checkbox"/>																								
Price-based selection process to maximise cost	<input type="checkbox"/>																								

	effectiveness	
	Any qualified provider	<input type="checkbox"/>
	National Commercial Agreements e.g. drugs, devices	<input type="checkbox"/>
	Procurement	<input type="checkbox"/>
	Other	<input type="checkbox"/>
Please specify: Click here to enter text.		

**B4 Place-based Commissioning**

B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)	<b>No</b> Please specify: Click here to enter text.
--	---

**Section C - Finance Impact**

**C1 Tariff/Pricing**

C1.1 How is the service contracted and/or charged? Only specify for the relevant section of the patient pathway	<i>Select all that apply:</i>	
	<b>Drugs</b>	Not separately charged – part of local or national tariffs <input type="checkbox"/>
		Excluded from tariff – pass through <input checked="" type="checkbox"/>
		Excluded from tariff - other <input type="checkbox"/>
	<b>Devices</b>	Not separately charged – part of local or national tariffs <input type="checkbox"/>
Excluded from tariff (excluding ZCM) – pass through <input type="checkbox"/>		



	<table border="1"> <tr> <td data-bbox="1079 97 1243 215"></td> <td data-bbox="1243 97 2056 156">Excluded from tariff (excluding ZCM) – other</td> <td data-bbox="2056 97 2130 156"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1079 97 1243 215"></td> <td data-bbox="1243 156 2056 215">Via Zero Cost Model</td> <td data-bbox="2056 156 2130 215"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1079 215 1243 630" rowspan="7"><b>Activity</b></td> <td data-bbox="1243 215 2056 274">Paid entirely by National Tariffs</td> <td data-bbox="2056 215 2130 274"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1243 274 2056 333">Paid entirely by Local Tariffs</td> <td data-bbox="2056 274 2130 333"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1243 333 2056 392">Partially paid by National Tariffs</td> <td data-bbox="2056 333 2130 392"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1243 392 2056 451">Partially paid by Local Tariffs</td> <td data-bbox="2056 392 2130 451"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1243 451 2056 510">Part/fully paid under a Block arrangement</td> <td data-bbox="2056 451 2130 510"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1243 510 2056 569">Part/fully paid under Pass-Through arrangements</td> <td data-bbox="2056 510 2130 569"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1243 569 2056 630">Part/fully paid under Other arrangements</td> <td data-bbox="2056 569 2130 630"><input checked="" type="checkbox"/></td> </tr> </table> <p data-bbox="1079 639 2130 671"><i>Year of care tariff</i></p>		Excluded from tariff (excluding ZCM) – other	<input type="checkbox"/>		Via Zero Cost Model	<input type="checkbox"/>	<b>Activity</b>	Paid entirely by National Tariffs	<input type="checkbox"/>	Paid entirely by Local Tariffs	<input type="checkbox"/>	Partially paid by National Tariffs	<input type="checkbox"/>	Partially paid by Local Tariffs	<input type="checkbox"/>	Part/fully paid under a Block arrangement	<input type="checkbox"/>	Part/fully paid under Pass-Through arrangements	<input type="checkbox"/>	Part/fully paid under Other arrangements	<input checked="" type="checkbox"/>
	Excluded from tariff (excluding ZCM) – other	<input type="checkbox"/>																				
	Via Zero Cost Model	<input type="checkbox"/>																				
<b>Activity</b>	Paid entirely by National Tariffs	<input type="checkbox"/>																				
	Paid entirely by Local Tariffs	<input type="checkbox"/>																				
	Partially paid by National Tariffs	<input type="checkbox"/>																				
	Partially paid by Local Tariffs	<input type="checkbox"/>																				
	Part/fully paid under a Block arrangement	<input type="checkbox"/>																				
	Part/fully paid under Pass-Through arrangements	<input type="checkbox"/>																				
	Part/fully paid under Other arrangements	<input checked="" type="checkbox"/>																				
<p data-bbox="91 735 344 767"><b>C1.2 Drug Costs</b></p> <p data-bbox="91 778 1048 887">Where not included in national or local tariffs, list each drug or combination, dosage, quantity, <b>list</b> price including VAT if applicable and any other key information e.g. Chemotherapy Regime.</p> <p data-bbox="91 898 1048 970">NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p>	<p data-bbox="1079 735 2130 954">Levofloxacin £2,181.53 per 28 days x 6 cycles pa = £13,089 pa. VAT is not payable as delivered through Homecare. It is assumed that for 75% of the patients Levofloxacin is taken in conjunction with a) Tobramycin -6 cycles of 28 days on 28 days off - List = £5,370/year/patient or b) Nebulised colistimethate sodium - 6 cycles of 28 days on 28 days off - List 2= £5,037/year/patient</p>																					
<p data-bbox="91 1031 371 1062"><b>C1.3 Device Costs</b></p> <p data-bbox="91 1074 1048 1182">Where not included in national or local tariff, list each element of the excluded device, quantity, <b>list or expected</b> price including VAT if applicable and any other key information.</p> <p data-bbox="91 1193 1048 1265">NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p>	<p data-bbox="1079 1031 1290 1062">Not applicable</p>																					
<p data-bbox="91 1326 801 1358"><b>C1.4 Activity Costs covered by National Tariffs</b></p>	<p data-bbox="1079 1326 2085 1358">Costs are covered by the Year of Care tariff. Patients receiving inhaled</p>																					

List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)	antibiotics for this indication will already be in Band 3											
C1.5 Will a prior approval mechanism be used to support implementation of the new policy that will require provider compliance to secure reimbursement?	<b>Yes</b> Please specify: Blueteq											
<b>C2 Average Cost per Patient</b>												
C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?  Are there any changes expected in year 6-10 which would impact the model?	<table border="1"> <tr><td>YR1</td><td>18,963</td></tr> <tr><td>YR2</td><td>18,963</td></tr> <tr><td>YR3</td><td>18,963</td></tr> <tr><td>YR4</td><td>18,963</td></tr> <tr><td>YR5</td><td>18,963</td></tr> </table>	YR1	18,963	YR2	18,963	YR3	18,963	YR4	18,963	YR5	18,963	<p>If yes, please specify: No</p>
YR1	18,963											
YR2	18,963											
YR3	18,963											
YR4	18,963											
YR5	18,963											
<b>C3 Overall Cost Impact of this Policy to NHS England</b>												
C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.	<b>Cost pressure</b> Please specify: Year 1 £654,450 Year 2 £981,675 Year 5 £1,963,350											

C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.	Not applicable
C3.3 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, has a methodology for the transfer of funds been identified, and calculated?	Not applicable
<b>C4 Overall cost impact of this policy to the NHS as a whole</b>	
C4.1 Specify the budget impact of the proposal on other parts of the NHS.	<p>Budget impact for CCGs:  <u><b>No impact on CCGs</b></u>  :  <u><b>No impact on providers</b></u>  Please specify:  Click here to enter text.</p>
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	<p><u><b>Cost pressure</b></u>  Please specify:  Year 1 £674,085; Year 2 £981,675; Year 5 £1,963,350</p>
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	Not applicable
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	<p><u><b>No</b></u>  Please specify:  Click here to enter text.</p>

**C5 Funding**

C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified, e.g. decommissioning less clinically or cost-effective services.

Specialised Commissioning resource envelope

**C6 Financial Risks Associated with Implementing this Policy**

C6.1 What are the material financial risks to implementing this policy?

There are no significant financial risks. Robust financial modelling based on reliable registry data has been undertaken.

C6.2 How can these risks be mitigated?

Not applicable

C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?

Robust financial modelling based on reliable registry data has been undertaken that allows confidence, as evidenced following launch of previous inhaled antibiotics. The patient pathway has been modelled and the proportion of patients that are expected to be treated in each clinical scenario has been estimated hence there is a small risk of error that could arise if this estimation is incorrect or clinical practise changes. The usage of this new drug may be impacted by the greater use of Ivacaftor which is expected to reduce the severity of CF in specific patient groups and could potentially reduce the need for Levofloxacin in the future. As this is hypothetical this scenario has not been included in the modelling.

C6.4 What scenario has been approved and why?

The scenario approved is to include Levofloxacin as an alternative inhaled therapy.

**C7 Value for Money**

C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?

**There is no published evidence of cost-effectiveness**

Please specify:

C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?

*Select all that apply:*

Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment	<input checked="" type="checkbox"/>
Available pricing data suggests the treatment is lower cost compared to current/comparator treatment	<input type="checkbox"/>
Available clinical practice data suggests the new treatment has the potential to improve value for money	<input type="checkbox"/>
Other data has been identified	<input type="checkbox"/>
No data has been identified	<input type="checkbox"/>
The data supports a high level of certainty about the impact on value	<input checked="" type="checkbox"/>
The data does not support a high level of certainty about the impact on value	<input type="checkbox"/>

Please specify:

[Click here to enter text.](#)

**C8 Cost Profile**

C8.1 Are there non-recurrent capital or revenue costs associated with this policy?

**No**

If yes, specify type and range:

[Click here to enter text.](#)

C8.2 If yes, confirm the source of funds to meet these costs.	Not applicable
---	----------------

Draft for public consultation