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Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	A11X04		
Policy Title	Selexipag in the treatment of Pulmonary Arterial Hypertension		
Accountable Commissioner	Kathy Blacker	Clinical Lead	Paul Corris
Finance Lead	Craig Holmes	Analytical Lead	Ceri Townley
Section K - Activity Impact			
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)	
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?	<p>K1.1 This policy proposes to not routinely commission the use of selexipag for certain patients with pulmonary arterial hypertension (PAH).</p> <p>Pulmonary hypertension services reported 6,484 active patients in 2014, of which around 45% had a diagnosis of PAH.ⁱ Thus, it is estimated that there were around 2,450 active patients in England with a pulmonary arterial hypertension diagnosis in 2014.ⁱⁱ</p> <p>The incidence of PAH is estimated at between 0.9 and 7.6 cases per million persons,ⁱⁱⁱ which is equivalent to 50 to 410 persons in England in 2014/15.^{iv} However, as noted in the policy proposition, general</p>	

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	<p>K1.2 What is the number of patients currently eligible for the treatment under the proposed policy?</p>	<p>incidence and prevalence rates may be underestimated as a result of mis- and/or undiagnosed patients.^v</p> <p>K1.2 The policy proposes not to routinely commission selexipag for those with PAH. The policy refers to patients with PAH with World Health Organisation (WHO) functional class (FC) II and III.^{vi} The policy was considered for patients falling into the following three clinical scenarios:</p> <p>The first clinical scenario is where patients are first starting targeted medical therapy, where monotherapy with PDE5 inhibitor (PDE5i) drugs is contraindicated (either because patients are intolerant or suffer from adverse reactions). This would be the case for an estimated c. 20-30 patients in the prevalent population in 2014/15.^{vii}</p> <p>The second clinical scenario refers to patients who currently use a PDE5i but suffer from clinical worsening. These patients would be considered for adding an endothelin receptor antagonist (ERA) to their existing treatments following a failure to stabilise on monotherapy.^{viii} It is estimated that approximately 500 patients in the prevalent population may fall under this scenario in 2014/15; however, it is estimated that clinicians would prefer to use ERAs in preference to selexipag, with only around 10% of this group opting for selexipag over an ERA.^{ix}</p> <p>The third clinical scenario would be a small group of patients that might use selexipag in combination with an ERA and a PDE5i.^x This group comprises ~ 5 - 15 suitable patients from the prevalent population in 2014/15 that would have been formally assessed and accepted as a suitable transplant candidate.^{xi}</p> <p>In total, approximately 525 – 550 patients from the prevalent population could be suitable for selexipag.</p> <p>Note that these figures relate to prevalence – the incidence or number</p>
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K1.3 What age group is the treatment indicated for?

of new patients joining the cohort each year would be much smaller.

K1.3 The policy indicates selexipag for use in adults (over 18 years).

K1.4 Describe the age distribution of the patient population taking up treatment?

K1.4 The median age of patients treated with disease targeted therapy (the drugs in the pathway covered by the present policy) is 59 years in 2013/14 (60 for women and 58 for men).^{xii} This has been stable over the past 5 years (it varied from 59 to 60).^{xiii} The interquartile range is 42-71 years.^{xiv}

In 2014 the number of female patients with pulmonary arterial hypertension was approximately twice as high as the number of male patients.^{xv}

K1.5 What is the current activity associated with currently routinely commissioned care for this group?

K1.5 Currently, patients under the three clinical scenarios above undergo the following treatments:

The **first clinical scenario** would currently use monotherapy of endothelin antagonist receptors (ERAs). This would be a used as a monotherapy after consideration for PDE5i. Bosentan (an ERA) is used approximately 69% of cases, ambrisentan (another ERA) in c. 31%.^{xvi}

The **second clinical scenario** would currently use PDE5i. In relation to PDE5is, sildenafil is used in circa 95% of cases, tadalafil in 5% of cases.^{xvii}

The **third clinical scenario** currently uses a combination of PDE5is, and ERAs.^{xviii} This group comprises ~5-15 patients.^{xix} Relative use of specific ERAs and PDE5is is estimated to be as set out in relation to

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K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?

K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years?

scenario 1 and 2.

No individual funding requests for **selexipag** for patients with PAH were submitted for the period 2013/14 to September 2015/16.^{xx}

K1.6 The growth of the number of patients who access pulmonary hypertension services is estimated at 5% per annum, whilst the number of patients who receive disease targeted drugs is estimated to grow at 7%.^{xxi}

K1.7 The target population would currently receive treatments outlined in K1.5. Based on patient numbers in K1.5 and the growth rate set out in K1.6, the **total number of patients from the prevalent population within the first clinical scenario** (receiving an **ERA**) is estimated at around: ^{xxii}

- Approx. 25-35 total persons in 2016/17
- Approx. 25-35 total persons in 2017/18
- Approx. 30-45 total persons in 2020/21.

In **clinical scenario 2**, the total number of prevalent patients (**receiving a PDE5i**) is estimated at around: ^{xxiii}

- Approx. 570 total persons in 2016/17
- Approx. 610 total persons in 2017/18
- Approx. 750 total persons in 2020/21.

In the **third clinical scenario**, the total number of patients is estimated at approximately 5 - 15 in future years.^{xxiv}

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	<p>K1.8 How is the population currently distributed geographically?</p>	<p>K1.8 Patients are distributed across England.</p> <p>For the number of patients active by specialised centre*, see the table below - PAH:</p> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <thead> <tr> <th style="text-align: center;">Specialised pulmonary hypertension centre</th> <th style="text-align: center;">Patients active and alive, 31/03/2014*</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Sheffield Teaching Hospitals NHS Foundation Trust</td> <td style="text-align: center;">823</td> </tr> <tr> <td style="text-align: center;">Royal Free London NHS Foundation Trust</td> <td style="text-align: center;">331</td> </tr> <tr> <td style="text-align: center;">Imperial College Healthcare NHS Trust</td> <td style="text-align: center;">430</td> </tr> <tr> <td style="text-align: center;">Royal Brompton and Harefield NHS Foundation Trust</td> <td style="text-align: center;">428</td> </tr> <tr> <td style="text-align: center;">Papworth Hospital NHS Foundation Trust</td> <td style="text-align: center;">291</td> </tr> <tr> <td style="text-align: center;">The Newcastle upon Tyne Hospitals NHS Foundation Trust</td> <td style="text-align: center;">252</td> </tr> </tbody> </table> <p><small>*Based on the National Audit of Pulmonary Hypertension 2014. Note that patients at these centres may not reside in England, and could reside elsewhere in the UK. They would not therefore be included in the estimates in K1.1.</small></p>	Specialised pulmonary hypertension centre	Patients active and alive, 31/03/2014*	Sheffield Teaching Hospitals NHS Foundation Trust	823	Royal Free London NHS Foundation Trust	331	Imperial College Healthcare NHS Trust	430	Royal Brompton and Harefield NHS Foundation Trust	428	Papworth Hospital NHS Foundation Trust	291	The Newcastle upon Tyne Hospitals NHS Foundation Trust	252
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<p>K2 Future Patient Population & Demography</p>	<p>K2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?</p>	<p>K2.1 The new policy proposes not to routinely commission selexipag as part of the existing policy for PAH.</p>														

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	<p>K2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival).</p> <p>K 2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details.</p> <p>K2.4 What is the resulting expected net increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10?</p>	<p>K2.2 The growth of the target population is likely to be affected by the following two factors: (a) an increase in prevalence; (b) an increase in the ratio of patients with pulmonary hypertension who receive disease targeted drugs. See K1.6.</p> <p>K2.3 None identified.</p> <p>K2.4 The proposed policy establishes a ‘not routinely commissioned’ proposal for the relevant population (the specific cohort set out in K1.2). The number of patients who fall outside of the cohort covered by the proposed policy, or for whom exceptionality might be demonstrated is likely to be very small.</p>
K3 Activity	<p>K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet.</p> <p>K3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet.</p> <p>K3.3 What will be the comparative</p>	<p>K3.1 The current activity is set out in K1.5; patients would be using ERAs, PDE5i, and/or prostaglandins.</p> <p>K3.2 As the recommendation for selexipag is to not routinely commission, activity would be as set out in K1.7.</p> <p>K3.3 The ‘do nothing’ scenario refers to current activity, assumed to be the ‘steady state’ rolled forward in future years. The future activity</p>

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		<ul style="list-style-type: none"> • Poor/no response to treatment <p>Drug therapies may also be withdrawn “at the end of life” phase.</p>
K5 Comparator (next best alternative treatment) Patient Pathway	<p>K5.1 If there is a ‘next best’ alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity.</p> <p>K5.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don’t continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.</p>	<p>K5.1 As K4.1-K4.3</p> <p>K5.2 As K4.1-K4.3</p>
K6 New Patient Pathway	<p>K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy.</p> <p>K6.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected</p>	<p>K6.1 Not applicable – policy progressing as not routinely commissioned.</p> <p>K6.2 Not applicable– policy progressing as not routinely commissioned.</p>

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	<p>to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.</p>	
K7 Treatment Setting	<p>K7.1 How is this treatment delivered to the patient?</p> <ul style="list-style-type: none"> ○ Acute Trust: Inpatient/Daycase/ Outpatient ○ Mental Health Provider: Inpatient/Outpatient ○ Community setting ○ Homecare delivery <p>K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? <i>e.g. service capacity</i></p>	<p>K7.1 The treatment would usually be for homecare delivery.^{xxv}</p> <p>K7.2 No change anticipated.</p>
K8 Coding	<p>K8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?</p> <p>K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)</p>	<p>K8.1 Selexipag is a high cost drug excluded from tariff, so it should be captured in the high cost drug dataset for routine commissioning.</p> <p>K8.2 The activity could be identified using ICD-10 codes.</p>

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K9 Monitoring	<p>K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?</p> <p>K9.2 If this treatment is a drug, what pharmacy monitoring is required?</p> <p>K9.3 What analytical information /monitoring/ reporting is required?</p> <p>K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?</p> <p>K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?</p> <p>K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?</p>	<p>K9.1 No change anticipated.</p> <p>K9.2 Not applicable – policy progressing as not routinely commissioned</p> <p>K9.3 Not applicable – policy progressing as not routinely commissioned.</p> <p>K9.4 No change anticipated.</p> <p>K9.5 Not applicable – policy progressing as not routinely commissioned.</p> <p>K9.6 No</p>
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	K9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. See also linked question in M1 below	K9.7 Not applicable – policy progressing as not routinely commissioned.
Section L - Service Impact		
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)
L1 Service Organisation	L1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)	L1.1 There are six tertiary PAH centres that provide diagnosis, intervention and support to patients with PAH. Only these centres are able to initiate disease targeted treatments as described in K4.1 - K6.3. <u>Current centres:</u> Imperial College Healthcare NHS Trust Royal Brompton & Harefield NHS Foundation Trust Royal Free London NHS Trust Papworth Hospital NHS Foundation Trust Sheffield Teaching Hospitals NHS Foundation Trust The Newcastle upon Tyne Hospitals NHS Foundation Trust
	L1.2 How will the proposed policy change the way the commissioned service is organised?	L1.2 No change anticipated.
L2 Geography & Access	L2.1 Where do current referrals come from?	L2.1 Current referrals come from consultant physicians, typically cardiology and respiratory consultants in secondary care. Occasionally referrals come from other specialities including haematology, rheumatology and infectious diseases.

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	<p>L2.2 Will the new policy change / restrict / expand the sources of referral?</p> <p>L2.3 Is the new policy likely to improve equity of access?</p> <p>L2.4 Is the new policy likely to improve equality of access / outcomes?</p>	<p>L2.2 No change anticipated.</p> <p>L2.3 Yes, through a consistent commissioning position across England.</p> <p>L2.4 Yes, through a consistent commissioning position across England.</p>
<p>L3 Implementation</p>	<p>L3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?</p> <p>L3.2 Is there a change in provider physical infrastructure required?</p> <p>L3.3 Is there a change in provider staffing required?</p> <p>L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?</p>	<p>L3.1 Not applicable – policy progressing as not routinely commissioned.</p> <p>L3.2 No change anticipated.</p> <p>L3.3 No change anticipated.</p> <p>L3.4 No change anticipated.</p>

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	<p>L3.5 Are there changes in the support services that need to be in place?</p> <p>L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)</p> <p>L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?</p> <p>L3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration)</p>	<p>L3.5 No change anticipated.</p> <p>L3.6 No change anticipated.</p> <p>L3.7 No change anticipated.</p> <p>L3.8 Not applicable – policy progressing as not routinely commissioned.</p>
L4 Collaborative Commissioning	L4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)	L4.1 No
Section M - Finance Impact		
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)
M1 Tariff	M1.1 Is this treatment paid under a	M1.1 No, see M1.2.

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	<p>national prices*, and if so which?</p> <p>M1.2 Is this treatment excluded from national prices?</p> <p>M1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical services?</p> <p>M1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes?</p> <p>M1.5 is VAT payable (Y/N) and if so has it been included in the costings?</p> <p>M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?</p>	<p>M1.2 Selexipag is a high cost drug excluded from tariff.</p> <p>M1.3 As an excluded drug, the price is subject to local negotiations. The list price is not publically available.</p> <p>M1.4 Not applicable.</p> <p>M1.5 No – the drug is delivered via homecare. VAT is not included in the calculations sections M2 and M3.^{xxvi}</p> <p>M1.6 No</p>
M2 Average Cost per Patient	M2.1 What is the revenue cost per patient in year 1?	M2.1 There would be no revenue cost as the policy proposes not to routinely commission selexipag for PAH.

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	<p>M2.2 What is the revenue cost per patient in future years (including follow up)?</p>	<p>For reference, the cost per patient per year (without homecare) of the drugs which are used instead of selexipag is:^{xxvii}</p> <ul style="list-style-type: none"> • c. £23,500 for bosentan (ERA) • c. £23,500 for ambrisentan (ERA) • c. £154 for sildenafil (PDE5i) • c. £6,400 for tadalafil (PDE5i) • c. £35,600 for iloprost (prostaglandin) • c. £120,000 for treprostinil (prostaglandin) • c. £35,000 for epoprostenol (prostaglandin) <p>As set out in M1.3 the list price for selexipag was not available for inclusion in this report.</p> <p>M2.2 There would be no revenue cost as the policy proposes not to routinely commission selexipag for PAH. For reference, the cost of the other PAH drugs per patient per year is the same as in M2.1; the length during which patients would pursue treatment is linked to life expectancy and also to the likelihood of developing complications.^{xxviii}</p>
<p>M3 Overall Cost Impact of this Policy to NHS England</p>	<p>M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England.</p> <p>M3.2 Where this has not been identified, set out the reasons why this cannot be measured.</p>	<p>M3.1 Cost neutral, as the position is to not routinely commission.</p> <p>M3.2 Not applicable.</p>
<p>M4 Overall cost impact of this policy to the NHS as a whole</p>	<p>M4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs).</p>	<p>M4.1 Cost neutral, as the position is to not routinely commission.</p>

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	<p>M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole.</p> <p>M4.3 Where this has not been identified, set out the reasons why this cannot be measured.</p> <p>M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?</p>	<p>M4.2 Cost neutral, as the position is to not routinely commission.</p> <p>M4.3 Not applicable.</p> <p>M4.4 None identified.</p>
<p>M5 Funding</p>	<p>M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified. <i>e.g. decommissioning less clinically or cost-effective services</i></p>	<p>M5.1 Not applicable.</p>
<p>M6 Financial Risks Associated with Implementing this Policy</p>	<p>M6.1 What are the material financial risks to implementing this policy?</p> <p>M6.2 Can these be mitigated, if so how?</p> <p>M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and</p>	<p>M6.1 Not applicable.</p> <p>M6.2 Not applicable.</p> <p>M6.3 Not applicable.</p>

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	most likely total cost scenarios?	
M7 Value for Money	<p>M7.1 What evidence is available that the treatment is cost effective? <i>e.g. NICE appraisal, clinical trials or peer reviewed literature</i></p> <p>M7.2 What issues or risks are associated with this assessment? <i>e.g. quality or availability of evidence</i></p>	<p>M7.1 To date no studies have been identified which evaluate the cost effectiveness of selexipag in the treatment of PAH.</p> <p>M7.2 Not applicable.</p>
M8 Cost Profile	<p>M8.1 Are there non-recurrent capital or revenue costs associated with this policy? <i>e.g. Transitional costs, periodical costs</i></p> <p>M8.2 If so, confirm the source of funds to meet these costs.</p>	<p>M8.1 Not applicable.</p> <p>M8.2 Not applicable.</p>

ⁱ National Audit of Pulmonary Hypertension, Report for the audit period April 2013 to March 2014, Fifth Annual Report: Key findings from the National Audit of Pulmonary Hypertension for the United Kingdom, Channel Islands, Gibraltar and the Isle of Man, 2014.

ⁱⁱ This is calculated as 84% (share of English population in UK population, ONS) multiplied by 45% of 6,484, see National Audit of Pulmonary Hypertension, Report for the audit period April 2013 to March 2014, Fifth Annual Report: Key findings from the National Audit of Pulmonary Hypertension for the United Kingdom, Channel Islands, Gibraltar and the Isle of Man, 2014, p.8. Figures for England were estimated based on UK figures and using the ratio of the population in England as a percentage of the UK population, based on ONS data: http://www.ons.gov.uk/ons/dcp171778_420462.pdf, last accessed: 10/02/2016.

ⁱⁱⁱ NHS England/A11/P/b, Publications Gateway Reference 01720, "Pulmonary Hypertension Policy, National policy for targeted therapies for the treatment of pulmonary hypertension in adults", May 2014, Pulmonary Hypertension CRG.

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^{iv} This is based on the incidence rate multiplied by the Office of National Statistics population estimate for England in 2014.

^v Frost et al., 2013, quoted in: NHS England/A11/P/b, Publications Gateway Reference 01720, “Pulmonary Hypertension Policy, National policy for targeted therapies for the treatment of pulmonary hypertension in adults”, May 2014, Pulmonary Hypertension CRG.

^{vi} Based on discussions with the policy working group.

^{vii} Based on discussions with the policy working group.

^{viii} Failure to stabilise refers to the lack of clinical worsening based on a number of measures, including 6 minute walking distance, haemodynamic markers, adverse events and toxicity, Borg dyspnoea scale, NT Pro-BMP level, WHO functional class, quality of life, and time to clinical worsening.

^{ix} Based on discussions with the policy working group.

^x Based on discussions with the policy working group.

^{xi} Based on discussions with the policy working group.

^{xii} National Audit of Pulmonary Hypertension, Report for the audit period April 2013 to March 2014, Fifth Annual Report: Key findings from the National Audit of Pulmonary Hypertension for the United Kingdom, Channel Islands, Gibraltar and the Isle of Man, 2014.

^{xiii} National Audit of Pulmonary Hypertension, Report for the audit period April 2013 to March 2014, Fifth Annual Report: Key findings from the National Audit of Pulmonary Hypertension for the United Kingdom, Channel Islands, Gibraltar and the Isle of Man, 2014.

^{xiv} National Audit of Pulmonary Hypertension, Report for the audit period April 2013 to March 2014, Fifth Annual Report: Key findings from the National Audit of Pulmonary Hypertension for the United Kingdom, Channel Islands, Gibraltar and the Isle of Man, 2014.

^{xv} This range is for 2012/13, based on National Audit of Pulmonary Hypertension, Report for the audit period April 2013 to March 2014, Fifth Annual Report: Key findings from the National Audit of Pulmonary Hypertension for the United Kingdom, Channel Islands, Gibraltar and the Isle of Man, 2014.

^{xvi} Analysis of data in National Audit of Pulmonary Hypertension, Report for the audit period April 2013 to March 2014, Fifth Annual Report: Key findings from the National Audit of Pulmonary Hypertension for the United Kingdom, Channel Islands, Gibraltar and the Isle of Man, 2014, p. 22.

^{xvii} Analysis of data in National Audit of Pulmonary Hypertension, Report for the audit period April 2013 to March 2014, Fifth Annual Report: Key findings from the National Audit of Pulmonary Hypertension for the United Kingdom, Channel Islands, Gibraltar and the Isle of Man, 2014, p. 22.

^{xviii} Analysis of data in National Audit of Pulmonary Hypertension, Report for the audit period April 2013 to March 2014, Fifth Annual Report: Key findings from the National Audit of Pulmonary Hypertension for the United Kingdom, Channel Islands, Gibraltar and the Isle of Man, 2014, p. 22.

^{xix} Based on discussions with the policy working group.

^{xx} Based on the national IFR database.

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^{xxi} Growth rates calculated based on historic audit data suggested growth rates over 10%. However, clinician experience indicated that recent growth has tapered, and an estimate of 5% and 7% has been used to estimate future increases in the population with PAH under treatment, and in the number of patients within the target population (a subset of those using medical therapy). These rates are applied to the population under treatment and the target population as set out in K1.1 and K1.2. Figures are rounded.

^{xxii} Based on the clinical scenario 1 as set out in K1.2 and the growth rate for the target population set out in K1.6. Figures are rounded.

^{xxiii} Based on the clinical scenario 1 as set out in K1.2 and the growth rate for the target population set out in K1.6. Figures are rounded.

^{xxiv} Figures are rounded. This population is not estimated to grow as per discussions with the policy working group.

^{xxv} As discussed with the policy working group

^{xxvi} VAT Notice 701/57: health professionals and pharmaceutical products, see section 3, accessed via: <https://www.gov.uk/government/publications/vat-notice-70157-health-professionals-and-pharmaceutical-products/vat-notice-70157-health-professionals-and-pharmaceutical-products> (gov.UK website), last accessed: 11/02/2016.

^{xxvii} All the costs listed below are from NHS England/A11/P/b, Publications Gateway Reference 01720, "Pulmonary Hypertension Policy , National policy for targeted therapies for the treatment of pulmonary hypertension in adults", May 2014, Pulmonary Hypertension CRG.

^{xxviii} For life expectancy of patients with pulmonary hypertension, see National Audit of Pulmonary Hypertension, Report for the audit period April 2013 to March 2014, Fifth Annual Report: Key findings from the National Audit of Pulmonary Hypertension for the United Kingdom, Channel Islands, Gibraltar and the Isle of Man, 2014, p. 25-29.