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Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	A01X07		
Policy Title	Continuous aztreonam lysine for cystic fibrosis (all ages)		
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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?	K1.1 This policy presents a position **to not routinely commission** the continuous use of aztreonam for certain patients with cystic fibrosis (CF). CF is a common life-limiting, inherited disease. The disease affects between 7,930 and 8,900 people in England in 2014.[i] [ii] The prevalence amongst the age group in which the treatment is intended for – those aged 6 years and older[iii] – is between 6,450 and 7,240.[iv] [v]	
	K.1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	K1.2 The policy proposes the continuous use of aztreonam for those that are contraindicated or intolerant to current antibiotics that treat chronic *Pseudomonas aeruginosa (P.aeruginosa)* in CF patients. *P. aeruginosa* is a type of bacteria that causes long term infection in the lungs; and of patients aged 6 or older with CF, 70% would be prescribed at least one	

		inhaled antibiotic.[vi] Of those patients that are prescribed an antibiotic, between 1% and 5% may require treatment with continuous aztreonam.[vii] There are therefore estimated to be c. 150 (range of c. 45 to 250) patients eligible for the treatment or under 4% of the prevalent population aged 6 and over.[viii]
	K1.3 What age group is the treatment indicated for?	K1.3 The treatment is indicated for adults and children aged 6 and older.
	K1.4 Describe the age distribution of the patient population taking up treatment?	K1.4 The age distribution for CF is skewed towards those under the age of 27 because the median age at death is approximately 28 for those with the condition.[ix]
	K1.5 What is the current activity associated with currently routinely commissioned care for this group?	K1.5 Patients that have chronic *P. aeruginosa*[x] associated with CF are treated with inhaled antibiotics. In the general CF population with *P. aeruginosa*, antibiotics are added in a stepwise approach, with **aztreonam lysine considered for use in cycle with another antibiotic** only when patients still present with exacerbations[xi] under treatments with the other antibiotics listed.[xii] (the % activity of all those with chronic *P. aeruginosa* is in parentheses):[xiii] • Colistin (83%) • Tobramycin (56%) • Aztreonam (13%) For those patients that require an escalation to aztreonam, **aztreonam may be given in cycles** with either tobramycin and colistimethate.[xiv] **Continuous use of aztreonam** would only be condisered after these treatment lines.

		For those **patients that might benefit from continuous aztreonam**, patients would currently be undertaking the following patterns of activity: [xv] • **aztreonam in a 28 day cycle with no alternative antibiotic** in the off cycle month. • **aztreonam in a 28 day cycle** with **tobramycin or colistemthate** despite continued deterioration. • **continuous aztreonam** The number of patients having each particular regimen could not be confirmed.
	K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?	K1.6 No change to the future **prevalence rate for CF** is anticipated; however, the prevalent population identified in K1.1 would grow in line with population growth and is estimated to be in the region of:[xvi] • 6,550 to 7,350 in 2016/17 (year 1) • 6,590 to 7,400 in 2017/18 (year 2) • 6,730 to 7,550 in 2020/21 (year 5) The number of patients with chronic *P.aeruginosa* may increase in the future if historic trends continue.[xvii] The number of **patients eligible for treatment** in future is estimated in the region of: [xviii] • 48 to 268 in 2016/17 (year 1) • 49 to 276 in 2017/18 (year 2) • 53 to 300 in 2020/21 (year 5)
	K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years?	K1.7 Under a do nothing scenario the activity for aztreonam (in continuous cycles) is assumed to increase in line with the growth in the eligible population noted in K1.6.[xix]
	K1.8 How is the population currently	K1.8 Across England – based on the evidence reviewed, no significant geographical differences in the disease have been identified.

	distributed geographically?	
K2 Future Patient Population & Demography	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?	K2.1 This policy proposes a **non-routine commissioning position**.
	K2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival)	K2.2 The factors that are likely to affect the growth in the target population are set out in K1.6 and K1.7. Other factors that may affect the population would be changes in survival rates of CF patients,[xx] and changes in the diagnosis rates for CF patients. However, the effect of these possible changes could not be quantified.
	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	K2.3 None identified.
	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?	K2.4 The proposed policy establishes that continuous aztreonam will not be routinely commissioned for the relevant population (the specific cohort set out in K1.2). There is expected to be no net change in the number of patients accessing the treatment under the policy as compared to the 'do nothing' scenario. 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.

K3 Activity	K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet 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 K3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted? Please details in accompanying excel sheet	K3.1 Current annual activity is identified in K1.5. K3.2 Given a non-routine commissioning position**,** activity would be as set out in K1.7.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. K3.3 The activity under to the do nothing would be as set out in K1.7.
K4 Existing Patient Pathway	K4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity. K4.2. What are the current	K4.1 Colistimethate is used first line when pulmonary function is normal but chronic Pseudomonas infection is evident. As per NICE guidance, colistimethate sodium dry powder inhaler can be used for patients who have previously been prescribed colistimethate sodium nebulised treatment and would continue to benefit from treatment but have otherwise become intolerant or have struggled to adhere with nebulised treatment and therefore would be switched to a more expensive product such as tobramycin nebules. In the same way that different nebulised antibiotics can be given as a continuous daily suppressive regime on a month on/month off basis, different dry powder inhalers can be used in an alternate monthly regime with other inhalers or nebulised treatments. Aztreonam would be used in cycle after earlier lines had failed. K4.2 Access based on whether chronic Pseudomonas infection has been

	treatment access criteria? K4.3 What are the current treatment stopping points?	diagnosed. K4.3 Lack of efficacy or intolerance to treatment.
K5 Comparator (next best alternative treatment) Patient Pathway	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. 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.	K5.1 Tobramycin should be considered if, despite continued therapy and good adherence to treatment, lung function continues to decline or there is a requirement for more than one course of IV antibiotics in the preceding year. This may be prescribed for alternate months in conjunction with colistimethate sodium. Aztreonam lysine may be considered if there is still progressive loss of lung function (defined as greater than 2% per year decline in FEV1 as % of predicted) or there is continued need for IV therapy for exacerbations i.e. more than two per year despite therapy with an alternating regimen of tobramycin and colistimethate. This may be prescribed as either alternating with colistimethate or tobramycin depending on the clinical response to those medications previously. K5.2 Approximately 70% of patients with cystic fibrosis (over the age of 6 years) are prescribed inhaled antibiotics. Consensus of clinical opinion estimates that 1-5% of those patients may not be suitable for the treatment regimes outlined in K5.1 due to lack of efficacy or intolerance to treatment.
K6 New Patient Pathway	K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy	K6.1 – K6.2 Not applicable as position is to not routinely commission.

	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 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.	
K7 Treatment Setting	K7.1 How is this treatment delivered to the patient? ○ Acute Trust: Inpatient/Daycase/ Outpatient ○ Mental Health Provider: Inpatient/Outpatient ○ Community setting ○ Homecare delivery K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? e.g. service capacity	K7.1 Aztreonam lysine is administered using a nebulizer system three times a day, which is available through home care delivery. There is no anticipated change in the current delivery model.[xxi] K7.2 Not applicable as position is to not routinely commission.
K8 Coding	K.8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?	K.8.1 The CF registry in the UK records all activity associated with Chronic *P. aeruginosa*; including the number of patients and the associated activity.[xxii] K8.2 Activity for the patient pathway is expected to be identified using the

	K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	CF registry, which includes the treatments and procedures available and their use amongst the CF population.
K9 Monitoring	K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule? K9.2 If this treatment is a drug, what pharmacy monitoring is required? K9.3 What analytical information /monitoring/ reporting is required? K9.4 What contract monitoring is required by supplier managers? What changes need to be in place? K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring? K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy? K9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. *See also linked*	K9.1-9.7 Not applicable as position is to not routinely commission.

	question in M1 below	
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 Treatment with inhaled therapies should only be initiated by a specialist cystic fibrosis centre. Continued supplies of a treatment may be prescribed by the specialist centre, by the network clinic in agreement with the specialist centre, or by the patient's GP in accordance with a shared-care agreement unless a patient access scheme would preclude this. However, during 2014-2016 it is the intention of NHS England to confine prescribing of these drugs to secondary care.[xxiii]
	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 Referrals can come from GPs, hospital specialists and paediatricians.
	L2.2 Will the new policy change / restrict / expand the sources of referral?	L2.2 No change anticipated.
	L2.3 Is the new policy likely to improve equity of access?	L2.3-2.4 No change.
	L2.4 Is the new policy likely to improve equality of access / outcomes?	
L3 Implementation	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?	L3.1-3.6 Not applicable as position is to not routinely commission.

	L3.2 Is there a change in provider physical infrastructure required? L3.3 Is there a change in provider staffing required? L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place? L3.5 Are there changes in the support services that need to be in place? L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor) L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers? 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)?	L3.7 No change anticipated. L3.8 Publication and notification of new policy.
L4 Collaborative Commissioning	L4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g.	L4.1 No

	future CCG lead, devolved commissioning arrangements)?	
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 national prices*, and if so which?	M1.1 Aztreonam is excluded from national tariff as a high cost drug.
	M1.2 Is this treatment excluded from national prices?	M1.2 The drug is excluded from national tariff.
	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?	M1.3 As a high cost drug, aztreonam would be subject local price negotiations. The cost per cycle for aztreonam is estimated at £2,182 per cycle. This is based on the NHS indicative price for aztreonam from the Dictionary of Medicines and assumes a dose of 75mg, three times a day.[xxiv]
	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.	M1.4 Not applicable.
	M1.5 is VAT payable (Y/N) and if so has it been included in the costings?	M1.5 VAT may be recoverable as the drug is for delivery via a homecare arrangement.[xxv]
	M1.6 Do you envisage a prior approval / funding authorisation being required to support	M1.6 Not applicable.

	implementation of the new policy?	
M2 Average Cost per Patient	M2.1 What is the revenue cost per patient in year 1?	M2.1 The revenue cost per patient (within the cohort as identified in K1.2) per year would be nil as the decision is to not routinely commission. For reference, the per patient cost of treatment in the first year is estimated to be £26,184 per patient receiving **continuous aztreonam**, plus homecare costs.[xxvi] However, as aztreonam is **not routinely commissioned** in continuous cycles the revenue cost per patient may be: • £13,092 per patient that receives **no alternative treatment** in the off cycle months[xxvii] • £20,900 to £23,800 per patient that receives **tobramycin** in the off cycle months[xxviii] • £14,600 to £18,900 per patient that recieves **colistin** in the off cycle months[xxix] If aztreonam were commissioned for routine use in patients with insufficient response to earlier lines of treatment, there might be a reduction in use of IV antibiotics and hospital bed days.
	M2.2 What is the revenue cost per patient in future years (including follow up)?	M2.2 The follow up cost is not anticipated to change as the current delivery model is expected to remain the same and patients may still receive a follow up every 6-8 weeks.[xxx] The cost per patient in future years for **aztreonam** lysine may be flat over the next ten years. The patent for aztreonam lysine is not due to expire until 2024[xxxi] and generics are not expected to enter the market within the next ten years.[xxxii] The cost per patient in future years for **tobramycin** is expected to be flat over the next ten years, as the patent is not due to expire until 2026.[xxxiii] The cost per patient in future years for **colistin** is expected to be flat as it is out of patent.

M3 Overall Cost Impact of this Policy to NHS England	M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England? M3.2 Where this has not been identified, set out the reasons why this cannot be measured?	M3.1 Cost neutral. The policy is to **not routinely commission** this treatment – no new patients within the specific cohort would be expected to start the treatment. M3.2 Not applicable.
M4 Overall cost impact of this policy to the NHS as a whole	M4.1 Indicate whether this is cost pressure, neutral, or cost saving for other parts of the NHS (e.g. providers, CCGs) M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole M4.3 Where this has not been identified, set out the reasons why this cannot be measured M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	M4.1 Cost neutral. M4.2 This policy is cost neutral. M4.3 Not applicable. M4.4 None identified.
M5 Funding	M5.1 Where a cost pressure is	M5.1 Not applicable.

	indicated, state known source of funds for investment, where identified e.g. decommissioning less clinically or cost-effective services	
M6 Financial	M6.1 What are the material financial risks to implementing this policy?	M6.1 Not applicable.
	M6.2 Can these be mitigated, if so how?	M6.2 Not applicable.
	M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	M6.3 Not applicable.
M7 Value for Money	M7.1 What evidence is available that the treatment is cost effective? *e.g. NICE appraisal, clinical trials or peer reviewed literature*	M7.1 One study was found that compared the cost of AZLI, taken three times a day on a 28 day on/28 day off cycle, with an analogous TOB treatment (Schechter et al., 2015). The study found that the total cost over 3 years of AZLI was 16% less than TOB (AZLI: £148,710 TOB: £176,268) [Original figures provided in US dollars and converted to the nearest full pound based on conversion rate on 17/11/2015 of £1 to $1.52 and is provided as a guideline for comparison only]. This saving was predominantly coming from the assumed reduction in number of hospitalisation, with a slight reduction in drug costs. It was also based on a US healthcare model. The study also found AZLI marginally increased the number of quality adjusted life years.
	M7.2 What issues or risks are associated with this assessment? *e.g. quality or availability of evidence*	M7.2 With the exception of (Trapnell et al., 2012), all of the RCTs were funded by Gilead, sole manufacturer of Cayston (trademark name for AZLI). Also there was considerable overlap in the authors of the majority of the RCTs and that many of these authors had received grants from Gilead, notably Oermann, McCoy, Retsch-Bogart, Gibson and Wainwright.
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? *e.g. Transitional costs,*	M8.1 No

	periodical costs M8.2 If so, confirm the source of funds to meet these costs.	M8.2 Not applicable.

[i] UK Cystic Fibrosis Registry. (2015). Cystic Fibrosis strength in numbers. UK Cystic Fibrosis Registry. [Online] accessible at: http://www.cysticfibrosis.org.uk/media/1596846/RegistryReport2014.pdf [Accessed 27/11/11].

[ii] After rebasing the number of CF patients registered on the UK CF registry to account for the proportion of the English population in the UK population (84%). In the UK as a whole there are between 10,583 and 9,432 people with CF. The lower estimate relates to the number of patients with complete data, while the upper estimate includes newly diagnosed patients that have not had their first annual review for the year.

[iii] Aztreonam is indicated in children aged 6 years and older in the policy proposition. NHS England (2014). Clinical Commissioning Policy: Inhaled Therapy for Adults and Children with Cystic Fibrosis. A01/P/b. [Online] accessible at: https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/01/a01-policy-inhld-thrpy-cf.pdf [Accessed 27/11/11].

[iv] There are 7,673 patients aged 6 and over registered on the CF registry. This is assumed to be the lower bound as it does not include newly diagnosed patients. Applying the ratio of 9,432:10,583 from footnote ii, the upper estimate for this age group is estimated to be 8,609. UK Cystic Fibrosis Registry. (2014).

[v] After rebasing the number of patients on the UK CF registry aged 6 and over to account for the proportion of patients in England. Cystic Fibrosis Registry. (2015). Cystic Fibrosis strength in numbers. UK Cystic Fibrosis Registry.

[vi] Based on discussions with the policy working group.

[vii] Based on discussions with the policy working group.

[viii] After applying these percentages to the target population in K1.1. The upper estimate is based on a high overall prevalence CF and assumes that 5% would be prescribed the treatment continuously. Whereas, the lower estimate is based on a low overall prevalence of CF and assumes that 1% would be prescribed the treatment continuously.

[ix] UK Cystic Fibrosis Registry. (2015). Cystic Fibrosis strength in numbers. UK Cystic Fibrosis Registry.

[x] The definition for chronic on the registry is three or more growths in a year.

[xi] The definition is typically more than two per year despite therapy with an alternating regimen of tobramycin and colistimethate. NHS England (2014). A01/P/b.

[xii] NHS England (2014). A01/P/b.

[xiii] UK Cystic Fibrosis Registry. (2015). Cystic Fibrosis strength in numbers. UK Cystic Fibrosis Registry. Tobramycin relates to the percentage on inhaled powder plus the percentage having the solution (assuming patients would not have both). Colistin relates to the percentage reported on colistin, colistimethate, or Promixin (assuming patients would only be on one of these three). Other aminoglycosides were used in 4.7% of cases.

[xiv] These antibiotics form the first and second line of treatments for the condition outlined in the NHSE commissioning policy for chronic Pseudomonas (A01/P/b 2014).

[xv] Based on discussions with the policy working group.

[xvi] The demographic specific growth rate is estimated using the cohorts from the ONS (2012) population projections to calculate a growth rate over the period 2015 to 2025. These are then adjusted to account for the age group six and over. Discussions with the policy working group indicated that higher apparent growth rates for prevalence noted in the CF registry reflected better data collection rather than a growing population.

[xvii] Between 2008 and 2014, the proportion of CF patients with chronic P. aeruginosa increased from 24.5% to 28%, which represents a compound annualised growth rate of 2.1%. There were 2,963 patients chronic P. aeruginosa in 2014, an increase from 2,098 in 2008. The number of CF patients registered increased from 8,513 to 10,583 over the same time. UK CF Registry Annual Data Report (2009), (2015).

[xviii] There could also be changes in the relative use of different antibiotics; however the future trajectory of this in relation to aztreonam could not be quantified in view of more limited time series data.

[xix] There could also be changes in the relative use of different antibiotics; however the future trajectory of this in relation to aztreonam could not be quantified in view of more limited time series data.

[xx] 'Life expectancy among people with cystic fibrosis has improved over the past few decades as a result of advances in care'. NICE (2015), Eyes on Evidence.

[xxi] Based on discussions with clinician and commissioner working group.

[xxii] Based on discussions with clinician and commissioner working group

[xxiii]NHS England (2014). A01/P/b.

[xxiv] This is the price for 'Cayston 75mg powder and solvent for nebuliser solution vials with Altera Nebuliser Handset (Gilead Sciences International Ltd) 84 vial', listed on the Dictionary of Medicines A pack of 84 vials equates to 28 days of three 75mg doses.

[xxv] Section 3.2, When can goods being provided on prescription be zero-rated for VAT purposes? https://www.gov.uk/government/publications/vat-notice-70157-health-professionals-and-pharmaceutical-products/vat-notice-70157-health-professionals-and-pharmaceutical-products

[xxvi] This assumes that each patient receives the equivalent of 12 cycles a year and that the cost per cycle (£2,182) is the same for patients that receive aztreonam continuously and for patients that receive aztreonam in a cycle basis. Scottish Medicines Consortium (2014), SMC No. (753/12); This assumes 6 cycles of aztreonam at a cost per cycle of £2,182 (DMD).

[xxvii] This assumes 6 cycles of aztreonam at a cost per cycle of £2,182 (DMD).

[xxviii] This assumes a cost per cycle of between £1,306 and £1,790 for tobramycin. The higher cost is for a dose regiment of 112mg via a Podhaler twice daily for 28 days, whereas the lower cost is for a dose regiment of 300mg via a nebuliser twice daily for 28 days. This also assumes a cost per cycle of £2,182 for aztreonam. DMD; SMC No. (753/12). The cost per cycle for aztreonam is listed on the DMD and the cost per year assumes 6 cycles of each of the two inhaled antibiotics.

[xxix] This assumes a cost per cycle of between £252 and £969 for colistimethate sodium and a cost per cycle of £2,182 for aztreonam. The higher cost is for a dose regiment of 125mg inhaled via a Turbospin inhaler twice a year, whereas the lower cost is for a dose regiment of 80mg via a nebuliser two or three times daily. DMD; SMC No. (753/12). The cost per cycle for aztreonam is listed on the DMD and the cost per year assumes 6 cycles of each of the two inhaled antibiotics.

[xxx] Based on discussions with clinician and commissioner working group.

[xxxi] The supplementary protection certificate is not set to expire until 2024 (UKMi data).

[xxxii] Based on discussions with clinician and commissioner working group.

[xxxiii] The supplementary protection certificate is not set to expire until after 2025/26 (UKMi data), which is beyond the time period considered in this document.