Shared Care Guideline for the management of Pseudomonas aeruginosa lung infection in Adult Non-Cystic Fibrosis Bronchiectasis

Nebulised antimicrobials: Nebulised Gentamicin, Tobramycin or Colistimethate Sodium

Executive Summary/ Critical Information.

Indication	Route & Dose	Key aims of treatment in the long term	Monitoring undertaken by specialist before requesting shared care	Ongoing monitoring to be undertaken by GP	Duration of treatment	Stopping criteria	Follow up (weeks/months)
Long term management of lung infection in Non-Cystic Fibrosis Bronchiectasis In patients with bronchiectasis, they are used either as	**Gentamicin (IV formulation for nebulisation)** (using alcohol and preservative free gentamicin 80mg in 2ml vial only) e.g: Cidomycin® brand **Adults: 80mg – 160 mg BD (nebulised)** Diluent need to be prescribe for an 80mg dose, 2ml (1 ampoule) of gentamicin 80mg/2ml injection solution should be mixed with 1-2ml sodium	**To improve symptoms, reduce the number of infective exacerbations and hospital admissions**	**Baseline monitoring prior to the treatment:** • **FEV_1, FVC** Only for patients able to perform lung function. Minimum annually by the initiating centre. • **Renal function** Annually by the initiating centre. Signs of renal dysfunction should be reported immediately to the specialist team. • **General Health of patient** GP to monitor patient's general health and to flag or seek advice from the initiating centre if ≥ 3 courses of rescue antibiotic treatment per year are required despite being on treatment • **Audiometry** Audiometry assessment by the initiating centre or the GP if any	**All specific monitoring for efficacy will be carried out by the Barts Health NHS Trust. Including patient's lung function, reduction in exacerbation rates and need for oral/intravenous antimicrobials,**	**The duration of treatment for each individual patient will be specified by the hospital consultant in the transfer letter.**	**Not tolerated** **Based on sputum results e.g. resistance, pseudomonas no longer cultured** **To be stopped by**	**Each patient to be followed up on a 3-6 monthly basis by respiratory team and annually by GP.**

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part of a Pseudomonas aeruginosa (PSA) eradication protocol or as long term treatment.	chloride 0.9%. For a 160mg dose, 4ml (2 ampoules) of gentamicin 80mg/ml injection should be used undiluted.		symptoms of dizziness, imbalance or hearing impairment are reported by the patient.	**improvement in subjective symptoms and general wellbeing will be assessed.**		**specialist only unless severe adverse event in community**	
	<u>Tobramycin</u> (nebulised) **Tymbrineb, TOBI® and Bramitob®** Adults = 300 mg twice a day for 28 days. **Tobramycin solution for injection (generic) phenol-free (Barts Health uses the IV tobramycin brands manufactured by Hospira or TEVA.)** Where possible it may be beneficial, but not essential to specify this on the prescription to help guide community pharmacies in sourcing these medications. Adults: 80mg – 160mg BD (nebulised) Dilute to a minimum 4ml						

	with sodium chloride 0.9% if required (for doses <160mg) Note: Patients should be maintained on the same brand if found to be tolerant). *Vantobra is another available preparation of tobramycin. All patients require a test dose with physiotherapist before continuing with treatment. Vantobra not currently used at St Barts, therefore would not be requested to continue in community.						

	<u>Colistimethate Sodium</u> (nebulised) **Colomycin®** (IV formulation for nebulisation) the usual doses are: Adults: 1-2 million units two to three times daily Please ensure the prescribing of diluent (sodium chloride 0.9% 2.5ml neb) this preparation negates the need for needles and syringes. **Promixin®** (powder for nebulisation) the usual doses are: Adults: 1 million units twice daily via I-Neb AAD system Please ensure the prescribing of diluents (1 – 4 ml water for injection or sodium chloride 0.9% - volume dependent on nebuliser system used). Test dose and training on the use of the nebuliser and reconstitution of the						

	medication will take place at the initiating centre. Note: generic colistimethate sodium injection is not licensed for nebulisation- only IV preparation Colomycin© brand.						

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Key Safety Notice (for instance: notification if prescribing must be brand specific or BNF cautionary and advisory warnings).

Gentamicin:

- Gentamicin should be used with caution in patients with renal impairment or pre-existing vestibular or hearing impairment.
- Concurrent and/or sequential use with other nephrotoxic or ototoxic medicines should be avoided.
    - Some diuretics can enhance aminoglycoside toxicity e.g. loop diuretics.
- There is a potential for systemic absorption of gentamicin following nebulisation. Adverse effects of systemic therapy include: ototoxicity, nephrotoxicity.

Cidomycin: https://www.medicines.org.uk/emc/product/1264

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Tobramycin:
Nebulised tobramycin use in patients with bronchiectasis is off-label but there is evidence of beneficial effects and it is supported by NICE and British Thoracic Society recommendations.[1,2]

- Patients who cannot tolerate Tymbrineb, Tobi® or Bramitob® may obtain benefit from using nebulised tobramycin injection [unlicensed use]; it may also provide a suitable lower-dose alternative for patients who have experienced adverse systemic side-effects with aminoglycosides, such as cochleotoxicity.
- The brand will be specified by the initiating secondary care specialist at the point of prescribing. It will be the responsibility of initiating specialist to advise the patient's General Practitioner if the patient is alternating with another nebulised antimicrobial or on an alternate" month on month off" basis.
- Tobramycin should be used in caution in patients with known or suspected renal, auditory, vestibular or neuromuscular dysfunction, or with severe, active haemoptysis
- Administration of tobramycin solution for inhalation is contraindicated in all patients with hypersensitivity to tobramycin, to any other aminoglycosides or to any of the excipients.
  Tobramycin injection (hospira): https://www.medicines.org.uk/emc/product/1425/smpc
  Tobi nebs: https://www.medicines.org.uk/emc/product/262/smpc
  Bramitob: https://www.medicines.org.uk/emc/product/6451
  Tymbrineb: https://www.medicines.org.uk/emc/product/8830

Colistimethate sodium:
Generic colistimethate sodium injection is not licensed for nebulisation.

- Concomitant use of colistimethate sodium with other medicinal products that are potentially nephrotoxic or neurotoxic (such as aminoglycoside or neuromuscular blocking drugs) should be undertaken with caution. (Further information can be found in the Summary of Product Characteristics- Promixin® and Colomycin®)
- Use with extreme caution in patients with porphyria
- It is contraindicated to patient who had hypersensitivity to colistimethate sodium (or other polymyxins) or to any excipients, patient with myasthenia gravis**.**
  Promixin: https://www.medicines.org.uk/emc/product/4
  Colomycin: https://www.medicines.org.uk/emc/product/9664/smpc

others

Treatment will be initiated by the consultant (28-day supply) and continued by GP.

[1]**BTS: https://www.brit-thoracic.org.uk/document-library/clinical-information/bronchiectasis/bts-guideline-for-non-cf-bronchiectasis**

[2]**NICE: https://www.nice.org.uk/advice/es12/chapter/Introduction-and-current-guidance**

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1. Background

Lung damage associated with persistent infection by Pseudomonas aeruginosa (PSA) is a major cause of morbidity and mortality in patients with bronchiectasis. Long-term treatment with nebulised antibiotics in patients with bronchiectasis aims to improve symptoms, reduce the number of infective exacerbations and hospital admissions and therefore reduce days of school and work as well as improve health status.
Nebulised antimicrobials provide high drug concentrations locally with low systemic absorption and reduced systemic adverse effects compared to intravenous antibiotics. In patients with bronchiectasis, they are used either as part of a Pseudomonas aeruginosa (PSA) eradication protocol or as long term treatment.

Nebulised antimicrobial used in this clinical situation includes Gentamicin, Tobramycin, Colistimethate Sodium. Treatment will be initiation by Hospital Consultant. Training on use of the nebuliser and reconstitution of the medication will take place at the initiating centre. Initiating centre will provide 28 medicine supply where continue supply should be followed up by GP.

Gentamicin:

Nebulised gentamicin is indicated in patients with chronic lung infection in non CF bronchiectasis. This is an unlicensed use and one of the treatment recommendation specified in the British Thoracic Society Non-CF bronchiectasis guideline. Nebulised gentamicin has been shown to reduce bacterial load and sputum volume, and improve breathlessness and exercise capacity (Lin HC, 1997). These findings were supported in a randomised controlled trial of 12 months of nebulised gentamicin or normal saline in patients with non CF bronchiectasis and chronic lung infection including, but not exclusively, Pseudomonas aeruginosa. There was a significant reduction in sputum bacterial density, 30% eradication of Pseudomonas and 92% eradication of other organisms, greater exercise capacity, fewer exacerbations, increased time to first exacerbation and improvements in quality of life scores (Murray MP, 2011).

Tobramycin:

Nebulised tobramycin use in patients with bronchiectasis is off-label but there is evidence of beneficial effects and it is supported by NICE and British Thoracic Society recommendations. The British Thoracic Society (BTS) guideline for non-CF bronchiectasis recommends that long term nebulised antibiotics should be considered in patients chronically infected with Pseudomonas aeruginosa having ≥3 exacerbations per year requiring antibiotic therapy or patients with fewer exacerbations that are causing significant morbidity.
Tobramycin nebuliser solution presented as Tymbrineb, Tobi® or Bramitob® in single use ampoules is indicated and licensed for children over 6 years & adults for the long term management of chronic Pseudomonas aeruginosa lung infection in Cystic Fibrosis (CF) patients. Tymbrineb, Tobi® and Bramitob® are specifically formulated for administration by inhalation and contain no preservatives, phenol nor bisulphates.

Prior to the development of Tymbrineb, Tobi® or Bramitob®, the injectable formulation of tobramycin was commonly given by nebulisation. Patients who cannot tolerate Tymbrineb, Tobi® or Bramitob® may obtain benefit from using nebulised tobramycin injection [unlicensed use]; it may also provide a suitable lower-dose alternative for patients who have experienced adverse systemic side-effects with aminoglycosides, such as cochleotoxicity.

Colistimethate Sodium

Colomycin® and Promixin® are licensed for nebulisation in patients with Cystic Fibrosis and the off-label use in non-CF bronchiectasis patients is supported by British Thoracic Society recommendations. The BTS guideline for non-CF bronchiectasis recommends that long term nebulised antibiotics should be considered in patients chronically

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infected with Pseudomonas aeruginosa having ≥3 exacerbations per year requiring antibiotic therapy or patients with fewer exacerbations that are causing significant morbidity.

2. Drug name, form, and licensed indications (unlicensed/off-label)

Gentamicin:
This is an unlicensed use and one of the treatment recommendation specified in the British Thoracic Society Non-CF bronchiectasis guideline

Alcohol and preservative free injectable gentamicin 80mg in 2ml vial (Cidomycin® is the preferred brand) should be use. This must be detailed on the prescription.

Tobramycin:
Tymbrineb, Tobi® or Bramitob® in single use ampoules is indicated and licensed for children over 6 years & adults for the long term management of chronic Pseudomonas aeruginosa lung infection in Cystic Fibrosis (CF) patients. The injectable formulation of tobramycin was commonly given by nebulisation[unlincensed use].

Colistimethate Sodium:
Colomycin® and Promixin® are licensed for nebulisation in patients with Cystic Fibrosis and the off-label use in non-CF bronchiectasis patients is supported by British Thoracic Society recommendations.
Note that generic colistimethate sodium injection is not licensed for nebulisation.

3. Dose and Administration

Gentamicin:

Usual initiation and maintenance dose:

- Adults: 80mg – 160 mg BD (nebulised)

Treatment can only be initiated by the specialist hospital consultant. The duration of treatment for each individual patient will be specified by the hospital consultant in the transfer letter.

- The first dose of the medicine should be given under hospital supervision in case of bronchospasm.
- **Dose should be prepared from alcohol and preservative free gentamicin 80mg in 2ml vial (Cidomycin® is the preferred brand). This must be detailed on the prescription.** The dose is then diluted to maximum of 4mL with Sodium Chloride 0.9% solution for nebulisation (for doses <160mg). For an 80mg dose, 2ml (1 ampoule) of gentamicin 80mg/2ml injection solution should be mixed with 1-2ml sodium chloride 0.9%. For a 160mg dose, 4ml (2 ampoules) of gentamicin 80mg/ml injection should be used undiluted.
- It should not be diluted or mixed with any other medicines or solutions apart from Colistin.
- Where patients are receiving several inhaled therapies antibiotics should be nebulised last.

Drug Product	Cost in primary care
Cidomycin 80mg/ml, 2 ml vial	£6.88/5 vials, £82.56/month (based on 80mg/day dose) £165.12/month (based on 160mg/day dose)
Sodium chloride 0.9% 2.5ml solution for nebulisation	20 dose units £8.52 1 month £25.56

Cost (based on BNF March 2021)

Tobramycin:

Tymbrineb, TOBI® and Bramitob®

- Adults = 300 mg twice a day for 28 days.
- Dose interval should be as close as possible to 12 hours and not less than 6-hours.
- Tymbrineb, TOBI® and Bramitob® must be stored in a refrigerator at 2-8°C in its original container. The entire content of one ampoule is nebulised over 15-mins using a PARI LC PLUS nebuliser or an alternative nebuliser as directed by the physiotherapist.
- The 28 day treatment period should be followed by a treatment free period of 28 days or alternating with another nebulised antibiotic.

Tobramycin solution for injection (generic) phenol-free

- Adults: 80mg – 160mg BD
- Dilute to a minimum 4ml with sodium chloride 0.9% if required (for doses <160mg)

- Before treatment with nebulised tobramycin is started, a trial must be carried out usually by a physiotherapist or specialist nurse to ensure that the patient does not experience adverse effects such as bronchoconstriction in secondary care.
- Barts Health uses the IV tobramycin brands Hospira or TEVA. Patients should be maintained on the same brand if found to be tolerant
- An inhaled or nebulised short acting β2 agonist such as salbutamol should be given beforehand if this is part of the patient's current regimen, and may also be required additionally in some patients whose Peak Expiratory Flow Rate (PEFR) is reduced after nebulisation of tobramycin
- Nebulised tobramycin should not be diluted or mixed with any other drug.
- Where patients are receiving several inhaled therapies, nebulised tobramycin should be nebulised last.

Drug Product	Cost in primary care
Tymbrineb 300mg/5ml nebuliser solution 5ml ampoules	£780 for 56 ampoules
Tobi® 300mg/5ml nebuliser solution 5ml ampoules	£1305.92 for 56 ampoules
Bramitob® 300mg/4ml nebuliser solution 4ml ampoules	£1187.00 for 56 ampoules
Phenol- free Tobramycin solution for injection (generic) [a]	NHS indicative price = £5.37 per vial. Cost for 28-days of treatment at 80mg or 160mg twice a day will be £300.72 to £601.44

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Sodium chloride 0.9% 2.5ml solution for nebulisation	20 dose units £8.52 1 month £25.56

[a]Intravenous preparation is not licensed for use as a nebuliser.

Costs (based on BNF March 2021)

Colistimethate Sodium:

Colomycin® the usual doses are:

- Adults: 1-2 million units two to three times daily

Promixin® the usual doses are:

- Adults: 1 million units twice daily via I-Neb AAD system

Treatment can only be initiated by the specialist hospital consultant who should also outline the duration of the treatment. Nebulised Colistimethate may be prescribed for 3 months in the case of Pseudomonas aeruginosa eradication, or on a long-term basis for those patients with chronic infection. In some patients colistimethate sodium is used on an alternate month basis with other nebulised antipseudomonal antibiotics e.g. inhaled aminoglycoside.

- Before treatment with nebulised Colomycin® or Promixin® is started, a trial must be carried out, usually by a physiotherapist or specialist nurse to ensure that the patient does not experience adverse effects such as bronchoconstriction.
- An inhaled or nebulised short acting β2 agonist such as salbutamol should be given beforehand if this is part of the patient's current regimen, and may also be required additionally in some patients whose Peak Expiratory Flow Rate (PEFR) is reduced after nebulisation of Colomycin®/Promixin®.
- The reconstitution and dilution instructions will be dependent on brand and nebuliser system. The dose should be dissolved in 1-4ml of water for injection or sodium chloride 0.9% dependent on brand and nebuliser system employed (this information will be communicated by the initiating centre). GP to ensure prescribing of diluents as communicated in transfer letter.
- Commonly 0.9% sodium chloride 2.5mL Steripoule® will be used to dissolve the Colomycin® powder, negating the need to draw up a diluent from larger ampoules, using needles and syringes at home.
- Colomycin® can be mixed with salbutamol to prevent bronchospasm. This can replace sodium chloride as the diluent. If patients require this, it will be indicated on the shared care request.
- Promixin® is exclusively nebulised via an I-neb hand-held nebuliser which is provided by the manufacturer. It is reconstituted with 1ml Sodium Chloride 0.9%
- Where patients are receiving several inhaled therapies, colistimethate should be nebulised last.

Drug Product	Cost in primary care
Colomycin® 2million unit powder for solution for injection vials (Teva UK Ltd)	£3.24 per unit dose (excluding VAT) Cost for 1-month based on twice daily dosing will be £194.40
Colomycin® 1million unit powder for solution for injection vials (Teva UK Ltd)	£1.80 per unit dose (excluding VAT) Cost for 1-month based on twice daily dosing will be £108
Promixin® 1million unit powder for nebuliser solution unit dose vials (Profile Pharma Ltd)	£6.80 per unit dose (excluding VAT) Cost for 1-month treatment based on twice daily dosing will be £408
Sodium chloride 0.9% 2.5ml solution for nebulisation	20 dose units £8.52 1 month £25.56

Costs (Based on BNF March 2021)

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4. Contraindications/Cautions

Gentamicin:

Warnings and Cautions

- Gentamicin should be used with caution in patients with renal impairment or pre-existing vestibular or hearing impairment.

Contraindications

- Hypersensitivity to gentamicin
- Myasthenia Gravis

Further information can be found in the gentamicin injection Summary of Product Characteristics.

Pregnancy and breastfeeding

Use of gentamicin in pregnancy or breast-feeding requires a careful risk/benefit analysis (poorly controlled lung infection is also a risk in pregnancy) which will be the responsibility of the specialist centre.

Limited further information can be found in the current British National Formulary and Summary of Product Characteristics.

Tobramycin:

Warnings and Cautions

- Known or suspected renal, auditory, vestibular or neuromuscular dysfunction, or with severe, active haemoptysis

Contraindications

- Administration of tobramycin solution for inhalation is contraindicated in all patients with hypersensitivity to tobramycin, to any other aminoglycosides or to any of the excipients.

Pregnancy and breastfeeding

The manufacturers of tobramycin solutions for inhalation advise that it should not be used during pregnancy or lactation unless the benefits to the mother outweigh the risks to the foetus or baby. Due to low systemic absorption and therefore low systemic concentrations associated with nebulised therapy, the decision to continue tobramycin solution for inhalation will be taken by the patient and the specialist centre after consideration of risks and benefits.

Systemic tobramycin is excreted in breast milk. It is not known if administration of Tymbrineb, TOBI® or Bramitob® will result in serum concentrations high enough for tobramycin to be detected in breast milk. The decision to continue tobramycin solution for inhalation will be taken by the patient and specialist centre after consideration of risks and benefits.

For comprehensive information please refer to the current British National Formulary and Summary of Product Characteristics for **Tymbrineb 300mg/5ml nebuliser solution**, **Bramitob® 300 mg/4ml Nebuliser Solution**, **Tobi® 300mg/5ml Nebuliser Solution** and **Tobramycin**

Colistimethate Sodium:

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Cautions

- Use with extreme caution in patients with porphyria
- Further information can be found in the **Summary of Product Characteristics- Promixin® and Colomycin®**

Contraindications

- Hypersensitivity to colistimethate sodium (or other polymyxins) or to any excipients
- Patients with myasthenia gravis.
- Further information can be found in the **Summary of Product Characteristics- Promixin® and Colomycin®**

For complete list of contraindications and cautions, please refer to the SPC: https://www.medicines.org.uk/emc.

Pregnancy and breastfeeding

Safety in human pregnancy has not been established. Animal studies do not indicate a teratogenic potential. However there is evidence that colistimethate sodium crosses the placenta and consequently there is potential for foetal toxicity if administered during pregnancy. Use of colistimethate sodium in pregnancy requires a careful risk/benefit analysis (poorly controlled lung infection is also a risk in pregnancy) which will be the responsibility of the specialist centre.

Colistimethate sodium is secreted in breast milk. Colistimethate sodium should be administered to breastfeeding women only when clearly needed. Each patient will be individually assessed by the specialist centre and informed whether or not to continue treatment.

For comprehensive information please refer to the current British National Formulary and Summary of Product Characteristics: Promixin and Colomycin

5. Drug interactions/side effects

Gentamicin:

- There is a potential for systemic absorption of gentamicin following nebulisation. Adverse effects of systemic therapy include: ototoxicity, nephrotoxicity.
- Concurrent and/or sequential use with other nephrotoxic or ototoxic medicines should be avoided. Some diuretics can enhance aminoglycoside toxicity e.g. loop diuretics.

Adverse effects	Symptoms/signs	Actions
Respiratory	Cough & Bronchospasm	May be relieved in some patients by using an inhaled bronchodilator prior to nebulisation
Oropharyngeal	Any suspicious of ototoxicity (e.g. tinnitus, hearing loss)	Discontinue treatment and inform initiating centre. GP to consider referral for audiometry testing where possible.
	Sore mouth, sore	Usually transient, advice to contact the centre if it persists

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	throat	for more than a week.

This only lists the key important ADRs- Further information can be found in the current British National Formulary and Summary of Product Characteristics.

Tobramycin:

Adverse effects	**Symptoms/signs**	**Actions**
Respiratory	Cough or bronchospasm.	May be relieved in some patients by using an inhaled bronchodilator prior to nebulisation.
	Voice alteration (including hoarseness), increased cough, rhinitis, pharyngitis.	Seek advice from the initiating centre
	Chest tightness, dyspnoea, haemoptysis, laryngitis, epistaxis	
Senses	Taste perversion, aphonia,	
Digestive System	Nausea, anorexia, mouth ulceration, vomiting, salivary hypersecretion, oral candidiasis	
Ear and labyrinth	Tinnitus, hearing loss, dizziness	Discontinue treatment and inform initiating centre. *GP to consider referral for audiometry testing where possible.*

This only lists the key important ADRs- For comprehensive information on cautions, contra-indications and interactions please refer to the current British National Formulary and Summary of Product Characteristics Tymbrineb 300mg/5ml nebuliser solution, Bramitob® 300 mg/4ml Nebuliser Solution and Tobi® 300mg/5ml Nebuliser Solution and tobramycin

Colistimethate Sodium:

This only lists the key important ADRs-For comprehensive information on cautions, contra-indications and interactions please refer to the current British National Formulary and Summary of Product Characteristics: Promixin® and Colomycin®

For complete list of drug interactions, please refer to the SPC: https://www.medicines.org.uk/emc.

Adverse effects	**Symptoms/signs**	**Actions**
Respiratory (Common)	Cough chest tightness or bronchospasm	May be relieved in some patients by using an inhaled bronchodilator prior to nebulisation
Digestive System	Sore mouth or throat has been reported and may be due to *Candida albicans* infection or hypersensitivity	Seek advice from the respiratory team
Skin	Rash may indicate hypersensitivity	Withdraw treatment and inform respiratory team

6. Monitoring and Responsibilities

Regular monitoring during treatment is essential to detect adverse reactions at an early stage and patients should be counselled about the risk factors and to report all signs and symptoms of toxicity. Note that specific efficacy monitoring will be undertaken by secondary care

Baseline	Sputum culture Test-dose, FEV_1 (percent predicted), renal function	
Monitoring	**FEV_1, FVC**	Only for patients able to perform lung function. Minimum annually by the initiating centre.
	Respiratory culture (sputum or cough swab)	The initiating centre at each clinic visit, at least annually.
	Renal function	Annually by the initiating centre. Signs of renal dysfunction should be reported immediately to the specialist team.
	General Health of patient	GP to monitor patient's general health and to flag or seek advice from the initiating centre if ≥ 3 courses of rescue antibiotic treatment per year are required despite being on treatment.

Results from any tests undertaken by the initiating centre will be included in the clinic letter.

a. Hospital specialist:

- Ensure that the patient/carer is an informed recipient in therapy.
- Ensure that patients understand their treatment regimen and any monitoring or follow up that is required (using advocacy if appropriate). Issue any local patient information leaflets where appropriate.

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- Ensure baseline investigations are normal before commencing treatment. Give the patient a patient held booklet for result monitoring if appropriate.
- Initiate treatment and prescribe until the GP formally agrees to share care (as a minimum, supply the first month of treatment or until patient is stabilised).
- Send a letter to the GP requesting shared care for this patient.
- Clinical and laboratory supervision of the patient by blood monitoring and routine clinic follow-up on a regular basis.
- Send a letter/results notification to the GP after each clinic attendance ensuring current dose, most recent blood results and frequency of monitoring are stated (unless otherwise covered by letter e.g. from Respiratory Clinical Nurse Specialist or Pharmacy Drug Monitoring Service).
- Where the GP is not performing the phlebotomy, the blood test form MUST be annotated to request that blood results are also copied to the GP. Results to be followed up by specialist centre.
- Evaluation of any reported adverse effects by GP or patient.
- Advise GP on review, duration or discontinuation of treatment where necessary. Where urgent action is required following tests the hospital team will telephone the patient and inform GP.
- Inform GP of patients who do not attend clinic appointments. Clinic appointments can be as frequent as 3 monthly in this patient group. This frequency would not be expected to change by engaging in shared care.
- Counsel the patient on contraception and what to do if pregnancy occurs. Document in the notes.
- Ensure that backup advice is available at all times.
- Ensure that the patient has received a flu vaccine prior to commencing treatment that is likely to cause immunosuppression. Document this in the patient notes and inform the GP it has been given

b. General Practitioner:

- Reply to the request for shared care as soon as practical (within 14 days) particularly if you are unable to accept the shared care agreement stating the reason(s) why.
- Prescribe the drug treatment in accordance with the specialist's recommendation
- Ensure that patients understand their treatment regimen and any monitoring or follow up that is required (using advocacy if appropriate).Contact the specialist for clarification where appropriate.
- Monitor patient's overall health and well-being.
- Report any adverse events to the consultant, where appropriate.
- Report any adverse events to the CSM, where appropriate.
- Help in monitoring the progression of disease
- Maintain a patient held monitoring booklet where used (where applicable)

c. Clinical Commissioning Group (CCG) -*Who may delegate this task to the Commissioning Support Unit (CSU)*

- To provide feedback to trusts via Trust Medicines Committee.
- To support GPs to make the decision whether or not to accept clinical responsibility for prescribing.
- To support trusts in resolving issues that may arise as a result of shared care.

d. Patient or parent/carer:

- Report any adverse effects to their GP and/or specialist
- Ensure they have a clear understanding of their treatment.
- Report any changes in disease symptoms to GP and/or specialist
- Alert GP and/or specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy
- Take/ administer the medication as prescribed
- Undertake any monitoring as requested by the GP and/or specialist

7. Contact Information

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Barts Health NHS Trust	
Adult Team	
Consultant via switchboard	**020 7377 7000**
Registrar on-call out of hours	**Aircall via switchboard**
Clinical Nurse Specialist (where appropriate)	**NA**
Hospital Pharmacist (where appropriate)	**020 346 56419** **bartshealth.pharmacyrespiratory@nhs.net**
Respiratory Physiotherapist	**Emily Martin/Annie Holdsworth** **Tel: 02037658390**
Paediatric Team	
Consultant via switchboard	**Tel: 0203 594 2474** **Fax: 0203 594 3258**
Registrar on-call out of hours	**Aircall via switchboard**
Clinical Nurse Specialist (where appropriate)	**Office: 0203 594 0491** **Pager: 07659 143 374** **Fax: bhnt.paediatric-CF-respiratory@nhs.net**
Hospital Pharmacist (where appropriate)	**Office: 02032460132**
Medicines Information Pharmacist (for both Adult and Paediatrics)	**0208 535 6971**
Primary Care Contacts	
Prescribing Advice for Tower Hamlets CCG	**0203 688 2556** thccg.medicinesoptimisation@nhs.net
Prescribing Advice for Newham CCG	**020 36882360** newccg.medicinesmanagement@nhs.net
Prescribing Advice for Waltham Forest CCG	**020 36882655** wfccg.medicinesoptimisation@nhs.net
Prescribing Advice for Barking and Dagenham, Havering and Redbridge (BHR) CCGs	**0208 8223074/6**

8. References

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This document has been produced in collaboration with the following organisations: Barts Health, NEL, Newham CCG, Tower Hamlets CCG, Waltham Forest CCG.

9. Document Management

Document ratification and history	
Produced by:	Barts Health, NEL CCG (TNW ICP)
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Appendix 1.

Shared Care Guideline: Prescribing Agreement

Section A: To be completed by the hospital consultant initiating the treatment

GP Practice Details:	**Patient Details:**
Name:	Name:
Tel No:	DOB:
Email (nhs.net):	NHS Number (10 digits):

Consultant Details:
Consultant Name:
Secretary Contact Details:
Tel No:
Email (nhs.net):

Diagnosis:	**Drug Name (to be prescribed by GP):** **Dose:** **Frequency:**

I will review the patient in clinic in weeks / months (*Delete as appropriate)*.

Dear

Your patient started treatment with the above drug for the above diagnosis on (insert date) and in my view; his/her condition is now stable.

The patient has given consent to treatment under a shared care prescribing agreement and has agreed to comply with instructions and follow up requirements.

I am requesting your agreement to sharing the care of this patient from (insert date) in accordance with the attached Shared Care Prescribing Guideline.

This patient was reviewed on (insert date). These are the results relevant for the drug and/or condition, as outlined in the shared care document:

Test	Baseline	Date

Please continue to monitor the patient as outlined in the shared care guidelines. Refer to the attached guidelines for monitoring criteria.

Other relevant information:

Consultant Signature:	Date:

Section B: To be completed by the GP and returned to the hospital consultant as detailed in Section A above [If returned via e-mail, use NHS.net email account ONLY]

Please sign and return your agreement to shared care within 14 days of receiving this request.

☐ Yes, I accept sharing care as per shared care prescribing guideline.

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☐ No, I am not willing to undertake shared care for this patient for the following reason: (Please give reason)		
GP Name:	GP Signature:	Date:

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