This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

Supply of clarithromycin tablets/oral suspension/oral solution for the treatment of acute bacterial sinusitis (rhinosinusitis) under the NHS England commissioned Pharmacy First service

Version Number 1.1

Change History	
Version and Date	**Change details**
Version 1.0 January 2024	New template

Version 1.1
January 2025
	• Minor typo corrected: Corrected “10 days or more” to “more than 10 days” in Inclusion criteria
	• TARGET TYI RTI leaflet information updated
	• Lercanidipine contraindicated with clarithromycin use highlighted in “Cautions including any relevant action to be taken” section
	• Addition of:
	  • “Chloroquine or hydroxychloroquine
	  • Lomitapide
	  • Ivabradine
	  • Medicines where concomitant use with a strong CYP 3A4 inhibitor (i.e. clarithromycin) is contraindicated (e.g.
	  ○ Avanafil
	  ○ Dronedarone
	  ○ Eplerenone
	  ○ Finerenone
	  ○ Lercanidipine
	  ○ Lurasidone
	  ○ Naloxegol
	  ○ Quetiapine)
	  • Any other medicine where concomitant use with clarithromycin is contraindicated” to “Drug Interactions” section

Version: 1.1
Reference Number: 6d
Valid from: 31/01/2024
Review date: 30/07/2026
Expiry date: 30/01/2027

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor	Prof. Sir Stephen Powis National Medical Director		29.04.25
Senior pharmacist	David Webb Chief Pharmaceutical Officer		29.04.25
Specialist in microbiology	Prof. Mark Wilcox National Clinical Director, IPC/AMR		29/04/25
Person signing on behalf of authorising body	David Webb Chief Pharmaceutical Officer		29.04.25

PGD DEVELOPMENT GROUP

Date PGD comes into effect:	31/01/2024
Review date	30/07/2026
Expiry date:	30/01/2027

This PGD has been peer reviewed by the Upper Respiratory Tract Infection (URTI) antimicrobial national PGD Short Life Working Group in accordance with their Terms of Reference. It has been reviewed by The Advisory Committee on Antimicrobial Prescribing, Resistance and Healthcare Associated Infection (APRHAI) to the Department of Health and Social Care (England) in November 2023.

Name	Designation
Dr Diane Ashiru-Oredope	Lead Pharmacist, HCAI, Fungal, AMR, AMU & Sepsis Division, UK Health Security Agency
Dr Imran Jawaid	GP and RCGP AMR representative
Dr Jeeves Wijesuriya	GP and Clinical Advisor to NHS England Primary Care Team and Vaccination and Screening Team
Jackie Lamberty	Medicines Governance Consultant Lead Pharmacist, UK Health Security Agency
Jo Jenkins	Lead Pharmacist Patient Group Directions and Medicines Mechanisms, Medicines Use and Safety Division, Specialist Pharmacy Service
Liz Cross	Advanced Nurse Practitioner QN
Dr Martin Williams	Consultant in Microbiology and Infectious Diseases
Temitope Odetunde	Head of Medicines Management
Nigel Gooding	Consultant Paediatric Pharmacist. Neonatal and Paediatric Pharmacist Group (NPPG) representative.
Kieran Reynolds (SLWG co-ordinator)	Specialist Pharmacist – Medicines Governance, Medicines Use and Safety Division, Specialist Pharmacy Service
Laura Whitney	NHS England Regional Antimicrobial Stewardship lead for the London region
Ms Wendy Smith	Consultant ENT Surgeon
Ghulam Haydar	Senior Policy Lead, Primary Care, Community Services and Strategy Directorate, NHS England

Characteristics of staff

Qualifications and professional registration	Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	• The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and be competent to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with the specification. • To deliver this service, the registered healthcare professional should have evidence of competence in the clinical skills and knowledge covered in the Centre for Pharmacy Postgraduate Education (CPPE) Pharmacy First Service self-assessment framework. • Before commencement of the service, the pharmacy contractor must ensure that pharmacists and pharmacy staff providing the service are competent to do so and be familiar with the clinical pathways, clinical protocol and PGDs. This may involve completion of training.
Competency assessment	• Individuals operating under this PGD must be assessed as competent or complete a self-declaration of competence to operate under this PGD (see an example authorisation record sheet in Appendix A). • Individuals operating under this PGD are advised to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Acute bacterial sinusitis (sinusitis) in children aged 12 years and over and adults where phenoxymethylpenicillin is not appropriate due to hypersensitivity.
Criteria for inclusion	• Informed consent • Individuals aged 12 years and over • Signs and symptoms of acute sinusitis using the appropriate NICE guidance • Diagnosis of acute sinusitis using the appropriate NICE CKS guidance • Presence of **ONE** of the following signs/symptoms (which suggests acute sinusitis is more likely): ○ Nasal blockage (obstruction/congestion) **OR** ○ Nasal discharge (anterior/posterior nasal drip) **AND ONE or more** of the following: ○ Facial pain/pressure (or headache) **OR** ○ Reduction (or loss) of the sense of smell (in adults) **OR** ○ Cough during the day or at night (in children) • Symptom duration of more than 10 days with no improvement • Presence of **TWO or more** of the following signs/symptoms (which suggests acute bacterial sinusitis is more likely): ○ Marked deterioration after an initial milder phase ○ Fever (>38°C) ○ Unremitting purulent nasal discharge ○ Severe localised unilateral pain, particularly pain over the teeth (toothache) and jaw • Persistent symptoms despite use of high-dose nasal corticosteroid (off-label) for 14 days **OR** • High-dose nasal corticosteroid (off-label) unsuitable • Known hypersensitivity to phenoxymethylpenicillin (penicillin V), any penicillin or any of the components within the formulation of phenoxymethylpenicillin formulations - see Summary of Product Characteristics. **Acceptable sources of allergy information include individual/carer/parent/guardian or National Care Record** **OR** • History of severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another beta-lactam antibiotic (e.g. cephalosporin, carbapenem or monobactam). **Acceptable sources of allergy information include individual/carer/parent/guardian or National Care Record**
Criteria for exclusion	• Consent refused and documented in the individual's clinical notes • Individuals under 12 years of age • Pregnancy or suspected pregnancy • Severely immunosuppressed individuals as defined in Chapter 28a Green book): ***Individuals with primary or acquired immunodeficiency states due to conditions including:***

	• *acute and chronic leukaemias, and clinically aggressive lymphomas (including Hodgkin's lymphoma) who are less than 12 months since achieving cure* • *individuals under follow up for a chronic lymphoproliferative disorders including haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma, Waldenstrom's macroglobulinemia and other plasma cell dyscrasias (N.B: this list not exhaustive)* • *immunosuppression due to HIV/AIDS with a current CD4 count of below 200 cells/µl.* • *primary or acquired cellular and combined immune deficiencies – those with lymphopaenia (<1,000 lymphocytes/ul) or with a functional lymphocyte disorder* • *those who have received an allogeneic (cells from a donor) or an autologous (using their own cells) stem cell transplant in the previous 24 months* • *those who have received a stem cell transplant more than 24 months ago but have ongoing immunosuppression or graft versus host disease (GVHD)* ***Individuals on immunosuppressive or immunomodulating therapy including:*** • *those who are receiving or have received in the past 6 months immunosuppressive chemotherapy or radiotherapy for any indication* • *those who are receiving or have received in the previous 6 months immunosuppressive therapy for a solid organ transplant* • *those who are receiving or have received in the previous 3 months targeted therapy for autoimmune disease, such as JAK inhibitors or biologic immune modulators including B-cell targeted therapies (including rituximab but for which a 6 month period should be considered immunosuppressive), monoclonal tumor necrosis factor inhibitors (TNFi), T-cell co-stimulation modulators, soluble TNF receptors, interleukin (IL)-6 receptor inhibitors., IL-17 inhibitors, IL 12/23 inhibitors, IL 23 inhibitors (N.B: this list is not exhaustive)* ***Individuals with chronic immune mediated inflammatory disease who are receiving or have received immunosuppressive therapy*** • *moderate to high dose corticosteroids (equivalent ≥20mg prednisolone per day) for more than 10 days in the previous month* • *long term moderate dose corticosteroids (equivalent to ≥10mg prednisolone per day for more than 4 weeks) in the previous 3 months* • *any non-biological oral immune modulating drugs e.g. methotrexate >20mg per week (oral and subcutaneous), azathioprine >3.0mg/kg/day; 6-mercaptopurine >1.5mg/kg/day, mycophenolate >1g/day) in the previous 3 months* • *certain combination therapies at individual doses lower than stated above, including those on ≥7.5mg prednisolone per day in combination with other immunosuppressants (other than hydroxychloroquine or sulfasalazine) and those receiving methotrexate (any dose) with leflunomide in the previous 3 months* ***Individuals who have received a short course of high dose steroids (equivalent >40mg prednisolone per day for more than a week) for any reason in the previous month.*** • Immunosuppressed individuals: individuals who are immunosuppressed or are currently taking immunosuppressants

	(including systemic corticosteroids*) or immune modulators, but who do not meet the definition of severe immunosuppression (see above). [For equivalent doses in children, see Chapter 6 Green Book] * does not include: ○ replacement corticosteroids for individuals with adrenal insufficiency ○ corticosteroid inhalers or corticosteroids applied topically (e.g. to the skin, ears, eyes, nasal cavity) ○ intra-articular, -bursal or -tendon corticosteroid injections. • Known hypersensitivity to clarithromycin, any macrolide or any of the components within the formulation – see Summary of Product Characteristics. **Acceptable sources of allergy information include individual/carer/parent/guardian or National Care Record**. • Inability to absorb oral medications and/or inability to swallow oral dosage formulations (i.e. tablets or oral suspension (or oral solution)) • Current long-term use of clarithromycin or another macrolide antibiotic (e.g. erythromycin for prophylaxis in asplenia, azithromycin for prophylaxis in individuals with COPD or bronchiectasis etc.) • Individuals following a ketogenic diet • Failed previous antibiotic for this episode of sinusitis • Nasal trauma • Epistaxis • Foreign body inserted into nasal passage • Recurrent sinusitis (4 or more annual episodes of sinusitis without persistent symptoms in the intervening periods) • Chronic sinusitis (sinusitis that causes symptoms that last for more than 12 weeks) • Anatomic defect(s) causing nasal obstruction • Suspected allergic or immunological cause of sinusitis • Co-morbidities complicating management such as nasal polyps. • Individual has signs of a more serious illness or condition (i.e. red flag symptoms) (e.g. intraorbital (within the eye) or periorbital (around the eye) complications: such as periorbital oedema (swelling) or cellulitis, displaced eyeball, double vision, ophthalmoplegia (paralysis/weakness of the eye muscles), or newly reduced visual acuity (reduced vision), intracranial complications such as swelling over the frontal bone, symptoms or signs of meningitis, severe frontal headache or focal neurological signs). • Any individual identified with symptoms of severe/life-threatening infection or systemic sepsis: refer urgently via ambulance. • Possible cancer: ○ Unilateral (one sided) polyp or mass or bloody nasal discharge present ○ Persistent unilateral symptoms, such as nasal obstruction, nasal discharge or nosebleeds, crusting or facial swelling • Known myasthenia gravis • Known history of QT prolongation (congenital or acquired), or ventricular cardiac arrhythmia, including torsades de pointe

	• Concomitant use of another medication known to cause QT prolongation (e.g. see Drug interactions section for further information or recommended resources include: CredibleMeds; registration required, or Sudden arrhythmic death syndrome (SADS) - Drugs to avoid) • Known electrolyte disturbances (hypokalaemia or hypomagnesaemia) • Known Chronic Kidney Disease (CKD) stages 4 or 5 (eGFR <30mL/min/1.73m^2) • Known or suspected severe liver disease • Known heart disease (e.g. coronary artery disease, severe cardiac insufficiency, bradycardia < 50 beats per minute) • Less than 3 days before receiving, or within 3 days after receiving, oral typhoid vaccine • Concurrent use of any interacting medicine as listed in Drug Interactions section of this PGD
Cautions including any relevant action to be taken	• Breastfeeding individuals: clarithromycin can be used in breastfeeding individuals (as per UKDILAS advice): monitor nursing infant for gastro-intestinal disturbances, oral candida infection, rashes, drowsiness, irritability, sweating and loss of appetite. • Caution should be exercised when supplying clarithromycin, a strong cytochrome P450 (CYP) 3A4 inhibitor to individuals taking the following medicine(s), that are known or suspected to be affected by clarithromycin: ○ **Coumarin anticoagulants (e.g. warfarin, acenocoumarol, phenindione):** rises in INR reported. Individuals should be advised to have their INR monitored while on treatment with clarithromycin and should be counselled re: seeing medical attention if any episode of bleeding develops while taking. ○ **Direct oral anticoagulants (DOACs)** (e.g. apixaban, dabigatran, edoxaban, rivaroxaban) Increased risk of bleeding when given with clarithromycin. Individuals should be advised to seek medical attention if any episode of bleeding develops while taking. ○ **Statins:** simvastatin use is contraindicated with clarithromycin. Counsel individuals taking other statins of the risk of rhabdomyolysis while taking clarithromycin and to seek medical attention if muscle pain develops. Consider withholding statin while taking clarithromycin to reduce risk of rhabdomyolysis. ○ **Calcium channel blockers:** lercanidipine use is contraindicated with clarithromycin. Risk of hypotension (low blood pressure) when taking clarithromycin with amlodipine, diltiazem, felodipine, nifedipine or verapamil. Counsel individuals of the risk and advise to avoid driving/operating machinery if light headed/dizzy. ○ **Oral hypoglycaemic agents (e.g. sulphonylureas)/insulin:** Use with clarithromycin can cause low blood glucose levels (hypoglycaemia). Advise individuals to monitor blood glucose levels more regularly while taking. ○ **Digoxin:** Concomitant use with clarithromycin can increase

	digoxin levels. Advise individuals of symptoms of digoxin toxicity (change in vision e.g. blurred vision, diarrhoea, confusion, dizziness, nausea, vomiting, skin rash) and to seek medical attention if any of these develop. • Caution should be exercised when supplying clarithromycin to individuals taking **medicines known to cause hypokalaemia** (e.g. diuretics, corticosteroids, xanthines): may cause electrolyte disturbances – monitoring may be indicated. Advise individuals to contact their prescriber to discuss need. • Caution should be exercised when supplying clarithromycin tablets or oral suspension (or oral solution) to individuals who should avoid the following excipients: ○ **Lactose, sucrose, fructose and sorbitol:** Individuals with rare hereditary problems of galactosaemia, galactose intolerance, total lactase deficiency, glucose-galactose malabsorption, sucrase-isomaltase deficiency, fructose-1,6-bisphosphatase deficiency (also known as hereditary fructose intolerance): check the individual list of excipients available in the SPC before supplying. ○ **Aspartame:** Individuals with phenylketonuria (PKU) must not use medicines containing aspartame. Check the individual list of excipients available in the SPC before supplying.
Specific information for suspected infection to be provided	Provide the Treating Your Infection Respiratory Tract Infection (TYI-RTI) patient information leaflet (TARGET RTI leaflet) (TARGET RTI leaflets in other languages are also available). Provide self-care advice including: - Paracetamol and ibuprofen (over the counter) can be used for pain and/or fever (where appropriate). (For further information see: Mild to moderate pain and NSAIDs-prescribing issues). - Little evidence that nasal saline (salt water) or nasal decongestants (over the counter) help relieve nasal congestion, but individuals may want to try them. [Water used should be boiled and cooled, sterile, distilled or filtered (using a < 1micron filter)]. - No evidence to support the use of oral decongestants, antihistamines, mucolytics, steam inhalation or warm face packs for this indication.
Action to be taken if the individual is excluded	• Record reasons for exclusion in the appropriate clinical record **Individuals where treatment is not indicated:** • Advise acute sinusitis is usually caused by a virus, can take 2–3 weeks to resolve, and most people will get better without antibiotics. • Where antibiotics are unlikely to of benefit: provide self-care advice • Advise individual/carer/parent/guardian to seek medical help if symptoms worsen rapidly or significantly or if they do not improve after 3 weeks. **Refer urgently to a prescriber for further assessment if:** • Individual is severely immunosuppressed or immunosuppressed

	• Individual is systemically unwell, but not showing signs or symptoms of sepsis
	• Possible cancer suspected:
	  ○ Unilateral (one sided) polyp or mass or bloody nasal discharge present
	  ○ Persistent unilateral symptoms, such as nasal obstruction, nasal discharge or nosebleeds, crusting or facial swelling
	• Individuals where treatment under this PGD is not indicated/permitted but upper respiratory symptoms are present and require further assessment.
	
	Refer urgently to A&E for further assessment if:
	• Signs of a more serious illness or condition (e.g. intraorbital (within the eye) or periorbital (around the eye) complications: such as periorbital oedema (swelling) or cellulitis, displaced eyeball, double vision, ophthalmoplegia (paralysis/weakness of the eye muscles), or newly reduced visual acuity (reduced vision),
	• Signs of intracranial complications such as swelling over the frontal bone, symptoms or signs of meningitis, severe frontal headache or focal neurological signs).
	
	If sepsis is suspected refer the individual urgently to A&E
	
	For children: see Healthier Together guidance (rhinosinusitis/persistent runny nose) for further information on appropriate signposting and parent information sheets.

Action to be taken if the individual/carer/parent/ guardian declines treatment	• Document advice given • Provide safety netting advice and advise individual/carer/parent/guardian of alternative treatment available using TARGET RTI leaflet (TARGET RTI leaflets in other languages are also available). • Refer to a prescriber if appropriate
Arrangements for referral for medical advice	Refer to the appropriate medical practitioner in the care pathway

Description of treatment

Name, strength & formulation of drug	Clarithromycin 250mg tablets Clarithromycin 500mg tablets Clarithromycin 125mg/5mL oral suspension (or oral solution) x 70mL Clarithromycin 250mg/5mL oral suspension (or oral solution) x 70mL
Legal category	POM
Route / method of administration	Orally, with water (taken with or without food). Tablets should be swallowed whole. *Note: Clarithromycin oral suspension (or oral solution) can cause a bitter after-taste. This can be avoided by drinking juice or water soon after intake of the oral suspension (or oral solution).*

Off-label use	**Temperature variations** Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the pharmacist must ensure the medicine remains pharmaceutically stable and appropriate for use if it is to be issued. Where medicines have been assessed by a pharmacist in accordance with national or specific product recommendations/manufacturer advice as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with the pharmacist. Manipulating solid dosage forms In the event of an individual being unable to swallow solid oral dosage formulations, and alternate liquid formulations not being readily available provide advice on how to give doses by crushing or dispersing tablets. Use in this way may be outside the product licence and is thus off-label. **Dispersing or crushing** Clarithromycin tablets are film-coated and can be crushed and mixed with liquid or soft food. Crushing tablets **should not** be undertaken by anyone with, or in the vicinity of someone with a macrolide allergy. **Dispersing tablets** To disperse the tablet: • Place the tablet in the barrel of a 10mL oral syringe • Replace the plunger • Draw up approximately 5mL of water and 2mL of air • Shake well and allow to disperse (this may take up to 10 minutes) • Ensure all contents of the oral syringe are given in the mouth Alternatively, the tablet may be mixed with 5 to 10mL of water in small glass or medicine cup and stirred well. **Masking the taste** The crushed tablet will taste bitter so it can be helpful to use a strongly flavoured drink (e.g. blackcurrant cordial) or food (e.g. jam, apple sauce, yoghurt) that the individual likes: • Use a small amount of food or drink (e.g. a teaspoonful) so you can be sure the individual eats it all and swallows the whole dose • It might be helpful to use an oral syringe for liquids • After mixing the crushed tablet with food or drink, give it straight

	away. Where a drug is recommended off-label consider, as part of the consent process, informing the individual/carer/parent/guardian that the drug is being offered in accordance with national guidance but that this is outside the product licence.
Dose and frequency of administration	**Children 12–17 years and adults:** 500mg twice daily (every 12 hours)
Duration of treatment	5 days **Treatment should be started immediately and 5 days of treatment completed**
Quantity to be supplied	In line with the Pharmacy First service specification the best value product to meet the clinical need should be supplied from those listed within this PGD. **Children 12–17 years and adults:** Appropriately labelled pack of 10 x 500mg tablets **OR** appropriately labelled pack of 20 x 250mg tablets **OR** appropriately labelled pack of 2 x 70mL x 250mg/5mL oral suspension (or oral solution) **OR** appropriately labelled pack of 3 x 70mL x 125mg/5mL oral suspension (or oral solution)
Storage	Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk

Drug interactions	Where it is known an individual is concurrently taking one of the following medicines, clarithromycin must not be supplied under this PGD and the individual referred to a prescriber:
	
	• Simvastatin, *lovastatin**
	• Astemizole, *cisapride**, domperidone, pimozide, *terfenadine**.
	• Ergotamine or dihydroergotamine
	• Ranolazine
	• Ticagrelor
	• Chloroquine or hydroxychloroquine
	• Colchicine
	• Midazolam (oral)
	• Lomitapide
	• Ivabradine
	• Typhoid vaccine (oral): see Criteria for exclusion
	• Medicines where concomitant use with a strong CYP 3A4 inhibitor (i.e. clarithromycin) is contraindicated (e.g.
	  ○ Avanafil
	  ○ Dronedarone
	  ○ Eplerenone
	  ○ Finerenone
	  ○ Lercanidipine
	  ○ Lurasidone
	  ○ Naloxegol
	  ○ Quetiapine)

	• Any medicine known to cause QT prolongation. For further information recommended resources include: CredibleMeds; registration required, or Sudden arrhythmic death syndrome (SADS) - Drugs to avoid
	• Medicines that are strong inducers of cytochrome P450 (CYP) and may reduce the efficacy of clarithromycin (e.g.
	  ○ Efavirenz, etravirine, nevirapine,
	  ○ Rifampicin, rifabutin, rifapentine,
	  ○ Phenytoin, carbamazepine, phenobarbital,
	  ○ St. John's wort.
	  ○ For further information recommended resources include:
	  ▪ Indiana University School of Medicine Drug Interactions Flockhart Table™
	  ▪ Mayo Clinic Labs Pharmacogenomic Association Table)
	• Any other medicine where concomitant use with clarithromycin is contraindicated.
	**May not be readily available in the UK*
	
	See BNF for all drugs that can interact with clarithromycin.
	
	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk

Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org The following side effects are listed in the product SPC/BNF as **very common or common** with clarithromycin (but may not reflect all reported side effects): • Gastrointestinal discomfort; including dyspepsia, diarrhoea, nausea and vomiting, abdominal pain, pancreatitis • Abnormal liver function tests • Decreased appetite • Dizziness • Headache • Hearing impairment • Insomnia • Skin rashes/reactions, hyperhidrosis, paresthesia • Taste altered • Vasodilation • Vision disorders Severe adverse reactions are rare, but anaphylaxis (delayed or immediate) has been reported and requires immediate medical treatment. In the event of a severe adverse reaction, the individual must be advised to stop treatment immediately and seek urgent medical advice.
Management of and	• Healthcare professionals and individuals/carers/parents/guardians are encouraged to report suspected adverse reactions to the

reporting procedure for adverse reactions	Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the individual's clinical record. • Report and document in accordance with organisation incident policy. • It is considered good practice to notify the individual's GP in the event of an adverse reaction.
Written information to be given to individual/carer/parent/ guardian	• Provide marketing authorisation holder's information leaflet (PIL) provided with the product. • Provide the TARGET RTI leaflet (TARGET RTI leaflets in other languages are also available). • Utilise TARGET antibiotic checklist for counselling individuals/carers/parents/guardians. • Give any additional information in accordance with the service specification.
Individual advice / follow up treatment	• Explain the dose, frequency and method of administration. • The individual/carer/parent/guardian should be advised to read the PIL. • Store reconstituted oral suspension (or oral solution) in accordance with the conditions as outlined in the individual product SPC (storage recommendations may vary between different reconstituted oral suspension (or oral solution) products). • Advise individual/carer/parent/guardian to seek medical advice if individual develops any red flag symptoms (e.g. intraorbital (within the eye) or periorbital (around the eye) complications: such as periorbital oedema (swelling) or cellulitis, displaced eyeball, double vision, ophthalmoplegia (paralysis/weakness of the eye muscles), or newly reduced visual acuity (reduced vision), intracranial complications such as swelling over the frontal bone, symptoms or signs of meningitis, severe frontal headache or focal neurological signs). • Symptoms should start to improve within 3-5 days of starting clarithromycin - advise individual to seek medical advice if no improvement within this time. • Advise individual/carer/parent/guardian to seek medical help if symptoms worsen rapidly or significantly or do not improve after completion of treatment course. • Advise individual/carer/parent/guardian to seek immediate medical attention (by calling 999 or going to A&E) if the individual develops signs or symptoms of sepsis. • Inform individual/carer/parent/guardian of possible side effects and their management. • Advise individual/carer/parent/guardian to take/give the medication at regular intervals and to finish the course. • If the individual is affected by dizziness or drowsiness advise them not to drive or operate machinery. • The individual/carer/parent/guardian should be advised to seek medical advice in the event of an adverse reaction or if any other new symptoms develop.

	• If a dose is missed, advise to refer to PIL supplied with the product • Advise individual/carer/parent/guardian to complete the full course even if symptoms improve. • Advise individual/carer/parent/guardian to return any unused medicines to a pharmacy for disposal: do not dispose of medicines in the bin, down the sink or toilet.

Records	Appropriate records must include the following:
	
	• That valid informed consent has been given
	• Individual's name, address and date of birth
	• Name of GP individual is registered with or record where an individual is not registered with a GP
	• Name and registration number of registered healthcare professional operating under this PGD
	• Specify how the individual has/has not met the criteria of the PGD
	• Relevant past and present medical history and medication history
	• Any known allergies and nature of reaction(s)
	• Name/dose/form/quantity of medicine supplied
	• Date and time of supply
	• Documentation of cautions as appropriate
	• Advice given, including advice given if individual excluded or declines treatment
	• Details of any adverse drug reactions and actions taken
	• Advice given about the medication including side effects, benefits, and when and what to do if any concerns.
	• Any follow up and/or referral arrangements made.
	• Any supply outside the terms of the product marketing authorisation
	• The supply must be entered in the Patient Medication Record (PMR)
	• That supply was made under a PGD
	• Any safety incidents, such as medication errors, near misses and suspected adverse events
	• Any additional requirements in accordance with the service specification:
	  • The pharmacy contractor will ensure that a notification of the provision of the service is sent to the patient's general practice on the day of provision or on the following working day. Where possible, this should be sent as a structured message in real-time via the NHS assured Pharmacy First IT system. In the absence of an automated digital solution or if there is a temporary problem with the system, this should be sent via NHSmail or hard copy.
	  • Where an action is required by the General Practice team (such as booking the patient in for a follow up or appointment) an action message or alternative form of an URGENT ACTION communication (rather than the standard post event message) must be sent to the practice.
	• All records should be kept in line with national guidance. This includes individual data, master copies of the PGD and lists of authorised practitioners.

	Records must be signed and dated (or a password controlled e-records). **All records must be clear, legible and contemporaneous.** **A record of all individuals receiving treatment under this PGD must also be kept for audit purposes in accordance with the service specification.**

Key references

Key references (last accessed November 2023)	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • Electronic BNF for children https://bnfc.nice.org.uk/ • Reference guide to consent for examination or treatment https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf • Medicines for Children. Clarithromycin for bacterial infections. https://www.medicinesforchildren.org.uk/medicines/clarithromycin-for-bacterial-infections/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • NHS Specialist Pharmacy Service. Using solid oral dosage form antibiotics in children https://www.sps.nhs.uk/articles/using-solid-oral-dosage-form-antibiotics-in-children/ • UK Sepsis Trust. Sepsis e-learning resources. https://sepsistrust.org/professional-resources/sepsis-e-learning/ • TARGET Treating your infection - Respiratory Tract Infection (TYI-RTI) leaflet https://elearning.rcgp.org.uk/mod/book/view.php?id=13511&chapterid=787 • TARGET Treating your infection - Respiratory Tract Infection (TYI-RTI) leaflet (available in other languages) https://elearning.rcgp.org.uk/mod/book/view.php?id=12647&chapterid=444 • NICE Clinical Knowledge Summary. Acute sinusitis. https://cks.nice.org.uk/topics/sinusitis/diagnosis/diagnosis-acute-sinusitis/ • NICE Guideline 79 [NG79]. Sinusitis (acute): antimicrobial prescribing. https://www.nice.org.uk/guidance/ng79

Appendix A – example registered health professional authorisation sheet (example – local versions/electronic systems may be used)

PGD Name/Version **Valid from:** **Expiry:**

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of insert name of organisation for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

Add details on how this information is to be retained according to organisation PGD policy.