

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 doxycycline capsules/dispersible tablets for the treatment of acute bacterial sinusitis (rhinosinusitis) under the NHS England commissioned Pharmacy First service

Version Number 1.0

| Change History              |              |                |  |
|-----------------------------|--------------|----------------|--|
| Version and<br>Date         |              | Change details |  |
| Version 1.0<br>January 2024 | New template |                |  |



## ORGANISATIONAL AUTHORISATIONS

| Name   | Job title and organisation                                  | Signature   | Date     |
|--|---|-------------|----------|
| Senior doctor<br>Professor Sir<br>Stephen Powis                                | National Medical<br>Director, NHS England                   | Stel Br.    | 11.12.23 |
| Senior pharmacist<br>David Webb  | Chief Pharmaceutical<br>Officer, NHS England                | AMA         | 08.12.23 |
| Specialist in<br>microbiology<br>Professor Mark<br>Wilcox                      | National Clinical<br>Director for AMR &<br>IPC, NHS England | Norte Line. | 11.12.23 |
| Person signing on<br>behalf of <u>authorising</u><br><u>body</u><br>David Webb | Chief Pharmaceutical<br>Officer, NHS England                | (ANA)       | 08.12.23 |



## 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-      | Lead Pharmacist, HCAI, Fungal, AMR, AMU & Sepsis Division, UK   |  |
| Oredope               | 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 | Specialist Pharmacist – Medicines Governance, Medicines Use and |  |
| co-ordinator)         | 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                             | <ul> <li>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.</li> <li>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.</li> <li>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.</li> </ul> |
| Competency<br>assessment                     | <ul> <li>Individuals operating under this PGD must be assessed as competent<br/>or complete a self-declaration of competence to operate under this<br/>PGD (see an example authorisation record sheet in <u>Appendix A</u>).</li> <li>Individuals operating under this PGD are advised to review their<br/>competency using the <u>NICE Competency Framework for health</u><br/><u>professionals using patient group directions</u></li> </ul>   |
| Ongoing training<br>and competency           | <ul> <li>Individuals operating under this PGD are personally responsible for<br/>ensuring they remain up to date with the use of all medicines and<br/>guidance included in the PGD - if any training needs are identified<br/>these should be discussed with the senior individual responsible for<br/>authorising individuals to act under the PGD and further training<br/>provided as required.</li> </ul>   |
|  | any medication rests with the individual registered health professional who and any associated organisational policies.  |



## Clinical condition or situation to which this PGD applies

| Clinical condition or<br>situation to which this<br>PGD applies | Acute bacterial sinusitis (rhinosinusitis) in children 12 years and over and adults where phenoxymethylpenicillin is not appropriate due to hypersensitivity.   |
|---|---|
| Criteria for inclusion  | <ul> <li>Informed consent</li> <li>Individuals aged 12 years and over</li> <li>Signs and symptoms of acute sinusitis using the appropriate <u>NICE guidance</u></li> <li>Diagnosis of acute sinusitis using the appropriate <u>NICE CKS guidance</u></li> <li>Presence of <b>ONE</b> of the following signs/symptoms (which suggests acute sinusitis is more likely):         <ul> <li>Nasal blockage (obstruction/congestion) OR</li> <li>Nasal discharge (anterior/posterior <u>nasal drip</u>)</li> <li><b>AND ONE or more</b> of the following:                 <ul> <li>Facial pain/pressure (or headache) OR</li> <li>Reduction (or loss) of the sense of smell (in adults) OR</li> <li>Cough during the day or at night (in children)</li> <li>Symptom duration of 10 days of more with little improvement</li> </ul> </li> </ul> </li> <li>Presence of <b>TWO or more</b> of the following signs/symptoms (which suggests acute bacterial sinusitis is more likely):         <ul> <li>Marked deterioration after an initial milder phase</li> <li>Fever (&gt;38°C)</li> <li>Unremitting purulent nasal discharge</li> <li>Severe localised unilateral pain, particularly pain over the teeth (toothache) and jaw</li> </ul> </li> <li>Persistent symptoms despite use of high-dose nasal corticosteroid (off-label) for 14 days OR</li> </ul> |
|   | <ul> <li>High-dose nasal corticosteroid (off-label) unsuitable</li> <li>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</li> <li>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 or National</li> </ul>   |
| Criteria for exclusion  | <ul> <li>Care Record</li> <li>Consent refused and documented in the individual's clinical notes</li> <li>Individuals under 12 years of age</li> <li>Pregnancy or suspected pregnancy</li> <li>Currently breastfeeding</li> <li>Severely immunosuppressed individuals as defined in <u>Chapter 28a</u><br/><u>Green book</u>):<br/>Individuals with primary or acquired immunodeficiency states due to<br/>conditions including:</li> </ul>  |



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



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|   | [For equivalent doses in children, see <u>Chapter 6 Green Book</u> ]<br>* does not include:   |
|   |   |
|   | <ul> <li>replacement corticosteroids for individuals with adrenal insufficiency</li> <li>corticosteroid inhalers or corticosteroids applied topically (e.g. to the</li> </ul> |
|   | skin, ears, eyes, nasal cavity)   |
|   | <ul> <li>intra-articular, -bursal or -tendon corticosteroid injections.</li> </ul>  |
| • | Known hypersensitivity to doxycycline, any tetracycline or any of the   |
| • | components within the formulation - see <u>Summary of Product</u>   |
|   | <u>Characteristics.</u> 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. capsules or dispersible tablets)  |
| • | Current long-term use of doxycycline or another tetracycline antibiotic   |
|   | (e.g. treatment of acne vulgaris, prophylaxis of malaria etc.)  |
| • | Individuals following a <u>ketogenic diet</u>   |
|   | 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, <u>symptoms or signs of meningitis</u> , 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:  |
|   | <ul> <li>Unilateral (one sided) polyp or mass or bloody nasal</li> </ul>  |
|   | discharge present   |
|   | <ul> <li>Persistent unilateral symptoms, such as nasal obstruction,</li> </ul>  |
|   | nasal discharge or nosebleeds, crusting or facial swelling  |
| • | Known myasthenia gravis   |
| • | Known systemic lupus erythematosus (SLE)  |
| • | Known oesophagitis or oesophageal ulceration  |
| • | Known porphyria   |
|   | Individuals taking enzyme inducing anti-epileptic medications   |
| • | (carbamazepine, fosphenytoin, phenobarbitone/phenobarbital,   |
|   | primidone, phenytoin)   |
|   | Individuals unable to separate administration times of interacting  |
| • | medicines (e.g. oral calcium/iron/magnesium/zinc/aluminium/bismuth  |
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|  | <ul> <li>salts (including some over the counter preparations (e.g. antacids)),<br/>lanthanum, sucralfate) and doxycycline by 2-3 hours</li> <li>Less than 3 days before receiving, or within 3 days after receiving,<br/>oral typhoid vaccine</li> <li>Concurrent use of any interacting medicine as listed in <u>Drug</u><br/><u>Interactions</u> section of this PGD</li> </ul>   |
| Cautions including<br>any relevant action to<br>be taken             | <ul> <li>Caution should be exercised when supplying doxycycline to individuals taking coumarin anticoagulants (e.g. warfarin, acenocoumarol, phenindione): rises in INR reported. Individuals should be advised to have their INR monitored while on treatment with flucloxacillin and should be counselled re: seeking medical attention if any episode of bleeding develops while taking.</li> <li>Caution should be exercised when supplying doxycycline capsules or dispersible tablets to individuals who should avoid the following excipients:         <ul> <li>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.</li> <li>Aspartame: Individuals with phenylketonuria (PKU) must not use medicines containing aspartame. Check the individual list of excipients available in the SPC before supplying.</li> </ul> </li> </ul> |
| Specific information<br>for suspected<br>infection to be<br>provided | <ul> <li>Provide the <u>Treating Your Infection Respiratory Tract Infection (TYI-RTI)</u><br/><u>patient information leaflet</u> (TARGET RTI leaflet)</li> <li>Provide <u>self-care advice</u> including: <ul> <li>Paracetamol and ibuprofen (over the counter) can be used for pain and/or fever (where appropriate). (For further information see: <u>Mild to moderate pain</u> and <u>NSAIDs-prescribing issues</u>).</li> <li>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 <u>boiled and cooled</u>, <u>sterile</u>, <u>distilled or filtered</u> (using a &lt; 1micron filter)].</li> <li>No evidence to support the use of oral decongestants, antihistamines, mucolytics, steam inhalation or warm face packs for this indication.</li> </ul> </li> </ul>   |
| Action to be taken if<br>the individual is<br>excluded               | <ul> <li>Record reasons for exclusion in the appropriate clinical records</li> <li>Individuals where treatment is not indicated: <ul> <li>Advise acute sinusitis is usually caused by a virus, can take 2–3 weeks to resolve, and most people will get better without antibiotics.</li> <li>Where antibiotics are unlikely to be of benefit: provide <u>self-care</u> advice</li> <li>Advise individual/carer/parent/guardian to seek medical help if symptoms worsen rapidly or significantly or if they do not improve after 3 weeks.</li> </ul> </li> </ul>  |



|  | Refer urgently to a prescriber for further assessment if:   |
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|  | <ul> <li>Individual is severely immunosuppressed or immunosuppressed</li> </ul>   |
|  | <ul> <li>Individual is systemically unwell, but not showing signs or symptoms</li> </ul>  |
|  | of <u>sepsis</u>  |
|  | Possible cancer suspected:  |
|  | <ul> <li>Unilateral (one sided) polyp or mass or bloody nasal<br/>disabaras present</li> </ul>  |
|  | <ul> <li>discharge present</li> <li>Persistent unilateral symptoms, such as nasal obstruction,</li> </ul>   |
|  | nasal discharge or nosebleeds, crusting or facial swelling  |
|  | <ul> <li>Individuals where treatment under this PGD is not</li> </ul>   |
|  | 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),   |
|  | <ul> <li>Signs of intracranial complications such as swelling over the frontal<br/>bone, symptoms or signs of meningitis, severe frontal headache or</li> </ul> |
|  | focal neurological signs).  |
|  |   |
|  | If <u>sepsis</u> 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                    | Document advice given   |
| the                                      | <ul> <li>Provide safety netting advice and advise</li> <li>individual/correr/parent/mandian of alternative treatment evailable</li> </ul>                       |
| individual/carer/paren                   | individual/carer/parent/guardian of alternative treatment available<br>using <u>TARGET RTI leaflet</u>  |
| t/guardian declines<br>treatment         | <ul> <li>Refer to a prescriber if appropriate</li> </ul>  |
|  | Refer to the appropriate medical practitioner in the care pathway   |
| Arrangements for<br>referral for medical | Neler to the appropriate medical practitioner in the care pathway   |
| advice                                   |   |
|  |   |

## **Description of treatment**

| Name, strength & formulation of drug | Doxycycline 50mg capsules<br>Doxycycline 100mg capsules<br>Doxycycline 100mg dispersible tablets  |
|--------------------------------------|---|
| Legal category                       | POM   |
| Route / method of administration     | 50mg or 100mg capsules: Orally, swallowed whole with plenty of water while sitting or standing well before (at least one hour before) bedtime.                            |
|                                      | 100mg dispersible tablets: Orally, after allowing to disperse in a small<br>amount of water, while sitting or standing well before (at least one hour<br>before) bedtime. |



|                                      | If gastric irritation occurs, doxycycline can be taken with food or milk.  |
|--------------------------------------|--|
| Off-label use                        | Temperature variations<br>Medicines should be stored according to the conditions detailed in the<br><u>Storage</u> section below. However, in the event of an inadvertent or<br>unavoidable deviation of these conditions the pharmacist must ensure<br>the medicine remains pharmaceutically stable and appropriate for use if it<br>is to be issued.<br>Where medicines have been assessed by a pharmacist in accordance<br>with national or specific product recommendations/manufacturer advice<br>as appropriate for continued use this would constitute off-label<br>administration under this PGD.    |
|                                      | The responsibility for the decision to release the affected medicines for use lies with the pharmacist.<br>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:<br>200mg as a single dose on the first day and then 100mg once daily for 4<br>days  |
| Duration of treatment                | 5 days<br>Treatment should be started immediately and 5 days of treatment<br>completed.  |
| Quantity to be<br>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.<br><b>Children 12-17 years and adults:</b><br>Appropriately labelled pack of 6 x 100mg capsules or 100mg dispersible tablets <b>OR</b> appropriately labelled pack of 12 x 50mg capsules.   |
| Storage                              | Stock must be securely stored according to organisation medicines policy<br>and in conditions in line with SPC, which is available from the electronic<br>Medicines Compendium website: <u>www.medicines.org.uk</u>  |
| Drug interactions                    | <ul> <li>Where it is known an individual is concurrently taking one of the following medicines, doxycycline must not be supplied under this PGD and the individual referred to a prescriber:</li> <li>Ciclosporin <ul> <li>Acitretin, alitretinoin, isotretinoin, tretinoin</li> <li>Lithium</li> <li>Typhoid vaccine (oral): see <u>Criteria for exclusion</u></li> </ul> </li> <li>See <u>BNF</u> for all drugs that can interact with doxycycline.</li> <li>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website:</li> </ul> |



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| 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:<br><u>www.medicines.org.uk</u> and BNF <u>www.bnf.org</u>  |
|   | <ul> <li>The following side effects are listed in the product SPC or BNF as common with doxycycline (but may not reflect all reported side effects): <ul> <li>Diarrhoea</li> <li>Hypersensitivity reactions</li> <li>Headache</li> <li>Nausea, vomiting</li> <li>Photosensitivity skin reactions</li> <li>Rash including maculopapular, erythematous rashes and Henoch-Schonlein purpura</li> <li>Urticaria</li> <li>Hypotension</li> <li>Pericarditis</li> <li>Tachycardia</li> <li>Dyspnoea</li> <li>Peripheral oedema</li> </ul> </li> </ul>   |
|   | <ul> <li>Photosensitivity reactions: advise individuals to avoid exposure to direct sunlight or ultraviolet light (including sunbeds and sun lamps) while taking doxycycline.</li> <li>If exposure to sunlight is unavoidable, advise individuals to protect their skin by: <ul> <li>Wearing clothes that cover them up,</li> <li>Wearing a hat and sunglasses,</li> <li>Using a high factor (minimum SPF 30) sunscreen or sunblock.</li> </ul> </li> <li>Gastric irritation: If individuals experience nausea or vomiting while taking doxycycline, advise them to take it with food or milk.</li> <li>Severe adverse reactions are rare, but <u>anaphylaxis</u> (delayed or immediate) has been reported and requires immediate medical treatment.</li> </ul> |
|   | 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<br>reporting procedure<br>for adverse reactions                           | <ul> <li>Healthcare professionals and individuals/carers/parents/guardians are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <u>https://yellowcard.mhra.gov.uk</u></li> <li>Record all adverse drug reactions (ADRs) in the individual's clinical record.</li> <li>Report and document in accordance with organisation incident policy.</li> <li>It is considered good practice to notify the individual's GP in the event of an adverse reaction.</li> </ul>   |
| Written or other<br>information to be<br>given to<br>individual/carer/paren<br>Version: 1.0 | <ul> <li>Provide marketing authorisation holder's information leaflet (PIL) provided with the product.</li> <li>Provide the <u>TARGET RTI leaflet</u>.</li> <li>Utilise <u>TARGET antibiotic checklist</u> for counselling</li> </ul>   |
| Reference Number: 6e<br>Valid from: 31/01/2024  |   |

Valid from: 31/01/2024 Review date: 30/07/2026 Expiry date: 30/01/2027



| t/guardian                                 | <ul> <li>individuals/carers/parents/guardians.</li> <li>Give any additional information in accordance with the service specification.</li> </ul>   |
|--|--|
| Individual advice /<br>follow up treatment | <ul> <li>Explain the dose, frequency and method of administration. If supplying dispersible tablets, advise individual/carer/parent/guardian to disperse (in a small amount of water) before taking. The individual/carer/parent/guardian should be advised to read the PIL.</li> <li>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).</li> <li>Symptoms should start to improve within 3-5 days of starting doxycycline - advise individual to seek medical advice if no improvement within this time.</li> <li>Advise individual/carer/parent/guardian to seek medical help if symptoms worsen rapidly or significantly or do not improve after completion of treatment course.</li> <li>Advise individual/carer/parent/guardian to seek immediate medical attention (by calling 999 or going to A&amp;E) if the individual develops signs or symptoms of sepsis.</li> <li>Inform individual/carer/parent/guardian of possible side effects and their management, including advice to swallow whole with plenty of</li> </ul> |
|  | <ul> <li>water while sitting or standing well before (at least one hour before) bedtime.</li> <li>Advise individual/carer/parent/guardian to take/give the medication at regular intervals (ideally the same time each day) and to finish the course.</li> <li>Advise individual/carer/parent/guardian that if the individual experiences nausea or vomiting while taking doxycycline, they can take it with food.</li> <li>Advise individual/carer/parent/guardian not to take antacids or preparations containing calcium/iron/magnesium/zinc/aluminium/bismuth salts (including some bought over the counter) within 2-3 hours of taking doxycycline. <i>Note: consider medicines contained within a medicines compliance aid (MCA or "blister pack") and tailor advice (i.e. alerting individual/carer/parent/guardian which medicines to omit while on treatment) to individual/carer/parent/guardian to avoid exposure to direct sunlight or ultraviolet light (including sunbeds and sun lamps) while taking doxycycline.</i></li> <li>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.</li> <li>If a dose is missed, advise to refer to PIL supplied with the product.</li> </ul>   |



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|         | <ul> <li>improve.</li> <li>Advise individual/carer/parent/guardian to return any unused<br/>medicines to a pharmacy for disposal: do not dispose of medicines in<br/>the bin, down the sink or toilet.</li> </ul>  |
| Records | Appropriate records must include the following:  |
| Records | <ul> <li>That valid informed consent has been given</li> <li>Individual's name, address and date of birth</li> <li>Name of GP individual is registered with or record where an individual is not registered with a GP</li> <li>Name and registration number of registered healthcare professional operating under this PGD</li> <li>Specify how the individual has/has not met the criteria of the PGD</li> <li>Relevant past and present medical history and medication history</li> <li>Any known allergies and nature of reaction(s)</li> <li>Name/dose/form/quantity of medicine supplied</li> <li>Date and time of supply</li> <li>Documentation of cautions as appropriate</li> <li>Advice given, including advice given if individual excluded or declines treatment</li> <li>Details of any adverse drug reactions and actions taken</li> <li>Advice given about the medication including side effects, benefits, and when and what to do if any concerns.</li> <li>Any follow up and/or referral arrangements made.</li> <li>Any supply outside the terms of the product marketing authorisation</li> <li>The supply must be entered in the Patient Medication Record (PMR)</li> <li>That supply was made under a PGD</li> <li>Any safety incidents, such as medication errors, near misses and suspected adverse events</li> <li>Any additional requirements in accordance with the service specification:</li> <li>The pharmacy contractor will ensure that a notification of the 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.</li> <li>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) individual data, master copies of the PGD and lists o</li></ul> |
|         | 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 | Electronic Medicines Compendium <a href="http://www.medicines.org.uk/">http://www.medicines.org.uk/</a> |
|----------------------|---|
| accessed November    | Electronic BNF <u>https://bnf.nice.org.uk/</u>  |
| 2023)                | <ul> <li>Electronic BNF for children <u>https://bnfc.nice.org.uk/</u></li> </ul>                        |
|                      | <ul> <li>Reference guide to consent for examination or treatment</li> </ul>                             |
|                      | https://assets.publishing.service.gov.uk/government/uploads/system/uploads                              |
|                      | /attachment_data/file/138296/dh_1036531pdf  |
|                      | <ul> <li>NICE Medicines practice guideline "Patient Group Directions"</li> </ul>                        |
|                      | https://www.nice.org.uk/guidance/mpg2   |
|                      | <ul> <li>UK Sepsis Trust. Sepsis e-learning resources.</li> </ul>                                       |
|                      | https://sepsistrust.org/professional-resources/sepsis-e-learning/                                       |
|                      | <ul> <li>TARGET Treating your infection - Respiratory Tract Infection (TYI-RTI)</li> </ul>              |
|                      | leaflet   |
|                      | https://elearning.rcgp.org.uk/mod/book/view.php?id=12647&chapterid=444                                  |
|                      | <ul> <li>NICE Clinical Knowledge Summary. Acute sinusitis.</li> </ul>                                   |
|                      | 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<br/>Direction and that I am willing and competent to work to it within my professional<br/>code of conduct.NameDesignationSignatureDate

| Name | Designation | Oignature | Date |
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#### 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.