

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 mometasone furoate monohydrate 50 micrograms/dose nasal spray for the treatment of acute sinusitis (rhinosinusitis) under the NHS England commissioned Pharmacy First service

Version Number 1.0

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

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor Professor Sir Stephen Powis	National Medical Director, NHS England		11.12.23
Senior pharmacist David Webb	Chief Pharmaceutical Officer, NHS England		08.12.23
Person signing on behalf of <u>authorising</u> <u>body</u> David Webb	Chief Pharmaceutical Officer, NHS England		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-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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 sinusitis (rhinosinusitis) in children aged 12 years and over and adults.
Criteria for inclusion	<ul style="list-style-type: none"> • 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): <ul style="list-style-type: none"> ○ Nasal blockage (obstruction/congestion) OR ○ Nasal discharge (anterior/posterior nasal drip) AND ONE or more of the following: <ul style="list-style-type: none"> ○ 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 10 days or more with little improvement • Presence of TWO or more of the following signs/symptoms (which suggests acute bacterial sinusitis is more likely): <ul style="list-style-type: none"> ○ 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
Criteria for exclusion	<ul style="list-style-type: none"> • Consent refused and documented in the individual's clinical notes • Individuals under 12 years of age • Pregnancy or suspected pregnancy in individuals under 16 years of age • Severely immunosuppressed individuals as defined in Chapter 28a Green book: <p>Individuals with primary or acquired immunodeficiency states due to conditions including:</p> <ul style="list-style-type: none"> • 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/ul. • 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

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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 $\geq 20\text{mg}$ prednisolone per day) for more than 10 days in the previous month
- long term moderate dose corticosteroids (equivalent to $\geq 10\text{mg}$ prednisolone per day for more than 4 weeks) in the previous 3 months
- any non-biological oral immune modulating drugs e.g. methotrexate $>20\text{mg}$ per week (oral and subcutaneous), azathioprine $>3.0\text{mg/kg/day}$; 6-mercaptopurine $>1.5\text{mg/kg/day}$, mycophenolate $>1\text{g/day}$ in the previous 3 months
- certain combination therapies at individual doses lower than stated above, including those on $\geq 7.5\text{mg}$ 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 $>40\text{mg}$ 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.
- Hypersensitivity to the active substance mometasone furoate, a glucocorticoid (or steroid), or to any of the excipients within the formulation - see [Summary of Product Characteristics](#). **Acceptable sources of allergy information include individual/carer/parent/guardian or National Care Record.**
- Failed previous intranasal steroid for this episode of sinusitis
- Symptom duration of less than 10 days
- Individuals with blurred vision or other visual disturbances
- Individuals with known or suspected glaucoma or raised intraocular pressure

	<ul style="list-style-type: none"> • Individual with untreated localised infection involving the nasal mucosa, such as herpes simplex. • Individuals who have experienced nasal trauma or undergone nasal surgery where full healing has not occurred • 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 • 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: <ul style="list-style-type: none"> ○ 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 currently taking oral, inhaled, topical or parenteral corticosteroids for any indication • Concurrent use of any interacting medicine as listed in Drug Interactions section of this PGD
Cautions including any relevant action to be taken	<p>Advise individual/carer/parent/guardian to seek medical advice if they develop any blurred vision or other visual disturbances during treatment (MHRA/CHM advice)</p>
Specific information for suspected infection to be provided	<p>Provide the Treating Your Infection Respiratory Tract Infection (TYI-RTI) patient information leaflet (TARGET RTI leaflet)</p> <p>Provide self-care advice including:</p> <ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> • Record reasons for exclusion in the appropriate clinical record.

<p>the individual is excluded</p>	<p>Individuals where treatment is not indicated:</p> <ul style="list-style-type: none"> • Advise acute sinusitis is usually caused by a virus, can take 2–3 weeks to resolve, and most people will get better without treatment. • Where intranasal steroids 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. <p>Refer urgently to a prescriber for further assessment if:</p> <ul style="list-style-type: none"> • Individual is severely immunosuppressed or immunosuppressed • Individual is systemically unwell, but not showing signs or symptoms of sepsis • Possible cancer suspected: <ul style="list-style-type: none"> ○ 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/permited but upper respiratory symptoms are present and require further assessment. <p>Refer urgently to A&E for further assessment if:</p> <ul style="list-style-type: none"> • 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). <p>If sepsis is suspected refer the individual urgently to A&E</p> <p>For children: see Healthier Together guidance (rhinosinusitis/persistent runny nose) for further information on appropriate signposting and parent information sheets.</p>
<p>Action to be taken if the individual/carer/parent/guardian declines treatment</p>	<ul style="list-style-type: none"> • Document advice given • Provide safety netting advice (detailed above) and advise individual/carer/parent/guardian of alternative treatment available using TARGET RTI leaflet • Refer to a prescriber if appropriate
<p>Arrangements for referral for medical advice</p>	<p>Refer to the appropriate medical practitioner in the care pathway</p>

Description of treatment

Name, strength & formulation of drug	Mometasone furoate monohydrate 50 micrograms/dose nasal spray
Legal category	POM <i>Note: ONLY the supply of the prescription-only medicine (POM) (and not pharmacy only (P)) is permitted under this PGD.</i>
Route / method of administration	Intranasal
Off-label use	<p>Mometasone furoate monohydrate 50 micrograms/dose nasal spray is not licensed for the treatment of sinusitis but use for this indication and at this dose is supported by NICE guidance.</p> <p>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.</p> <p>Where medicines have been assessed by a pharmacist in accordance with national or specific product recommendations/manufacture advice as appropriate for continued use this would constitute off-label administration under this PGD.</p> <p>The responsibility for the decision to release the affected medicines for use lies with the pharmacist.</p> <p>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.</p>
Dose and frequency of administration	Children 12-17 years and adults: Two actuations (50 micrograms/actuation) in each nostril twice daily (total dose 200 micrograms twice daily).
Duration of treatment	14 days
Quantity to be supplied	Children 12-17 years and adults: Appropriately labelled pack of 1 x 18g nasal sprays Ensure a minimum of 112 actuations of 50microgram/actuation is supplied.
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	<p>The BNF states that interactions do not generally apply to corticosteroids used for topical action (including inhalation), however co-administration with the CYP3A inhibitors listed below is not permitted under this PGD.</p> <p>Mometasone furoate monohydrate nasal spray must not be supplied to any individual concurrently taking (moderate or potent CYP 3A4</p>

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	<p>inhibitors) including:</p> <ul style="list-style-type: none"> • Ciprofloxacin • Clarithromycin • Erythromycin • Diltiazem • Fluconazole • Itraconazole • Ketoconazole • Posaconazole • Ritonavir • Cobicistat • Verapamil • Voriconazole • Goldenseal • Any other cytochrome P450 3A4 inhibitor (for further information recommended resources include: <ul style="list-style-type: none"> ○ Indiana University School of Medicine Drug Interactions Flockhart Table™ ○ Mayo Clinic Labs Pharmacogenomic Association Table) <p>This list is not exhaustive. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>
<p>Identification & management of adverse reactions</p>	<p>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</p> <p>The following side effects are listed in the product SPC or BNF as very common or common with intranasal mometasone (or other intranasal steroids) (but may not reflect all reported side effects):</p> <ul style="list-style-type: none"> • Epistaxis • Headache • Nasal burning • Pharyngitis • Nasal irritation • Throat irritation • Nasal ulceration • Upper respiratory tract infection • Altered smell • Altered taste <p>Severe adverse reactions are rare, but anaphylaxis (delayed or immediate) has been reported and requires immediate medical treatment.</p> <p>In the event of a severe adverse reaction, the individual must be advised to stop treatment immediately and seek urgent medical advice.</p> <p>Systemic absorption may follow nasal administration, particularly if high doses are used or if treatment is prolonged. Therefore, also consider the side-effects of systemic corticosteroids.</p>

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Management of and reporting procedure for adverse reactions	<ul style="list-style-type: none"> 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: 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 or other information to be given to individual/carer/parent/guardian	<ul style="list-style-type: none"> Provide marketing authorisation holder's information leaflet (PIL) provided with the product. Provide the TARGET RTI leaflet. Give any additional information in accordance with the service specification.
Individual advice / follow up treatment	<ul style="list-style-type: none"> Explain the dose, frequency and method of administration including how to use the nasal spray. The individual/carer/parent/guardian should be advised to read the PIL. Ensure individual/carer/parent/guardian is informed that the individual should NOT sniff immediately after using the nasal spray to ensure the administered dose is retained locally Advise individual/carer/parent/guardian to seek medical advice if the individual develops any blurred vision or other visual disturbances during treatment (MHRA/CHM advice) 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). 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. Advise individual/carer/parent/guardian to seek medical advice if symptoms worsen. Advise individual/carer/parent/guardian to use/give the medication at regular intervals and to finish the course even if symptoms improve. 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. <i>Note: nosebleeds associated with treatment are generally self-limiting, mild in severity and have only been reported for treatment durations longer than permitted under this PGD.</i> If a dose is missed, advise to refer to PIL supplied with the product. 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:

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- 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

<p>Key references (last accessed November 2023)</p>	<ul style="list-style-type: none"> • 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 • NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2 • TARGET Treating your infection - Respiratory Tract Infection (TYI-RTI) leaflet 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 • Society for Endocrinology. Exogenous steroids treatment in adults. Adrenal insufficiency and adrenal crisis-who is at risk and how should they be managed safely. https://www.endocrinology.org/media/4091/spssfe_supporting_sec_-_final_10032021-1.pdf
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**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.

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