

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 valaciclovir tablets for the treatment of shingles (herpes zoster) infection 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
Specialist in microbiology Professor Mark Wilcox	National Clinical Director for AMR & IPC, NHS England		11.12.23
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
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This PGD has been peer reviewed by the shingles 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 (APRHA) 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
Dr Naomi Fleming	NHS England Regional Antimicrobial Stewardship lead for the East of England
Gill Damant	NHS England Regional Antimicrobial Stewardship lead for the North West region
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 Michelle Toleman	Consultant Microbiologist
Temitope Odetunde	Head of Medicines Management
Kieran Reynolds (SLWG co-ordinator)	Specialist Pharmacist – Medicines Governance, Medicines Use and Safety Division, Specialist Pharmacy Service
Dr Stephanie Gallard	GP (Dermatology Special Interest)
Rob Proctor	Senior Policy and National Pharmacy Integration Lead, Primary Care, Community Services and Strategy Directorate, NHS England
Dr Mathew Donati	Consultant Medical Virologist/ Clinical Head of Virology, UK Health Security Agency

Initial PGD drafted by Alison Evans on behalf of Medicines Use and Safety Division, Specialist Pharmacy Service

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	Shingles (herpes zoster) infection in adults aged 18 years and over.
Criteria for inclusion	<ul style="list-style-type: none"> • Informed consent • Adults aged 18 years or over • Diagnosis of shingles following the appropriate NICE CKS guidance • Diagnosed with shingles within 72 hours of rash onset AND ANY of the following: <ul style="list-style-type: none"> ○ Non-truncal involvement (e.g. shingles affecting the neck, limbs, or perineum). ○ Moderate or severe pain (consider using a validated pain assessment scale, such as the Visual Analog Scale or Pain Scales produced by the British Pain Society (available in multiple languages)) ○ Moderate or severe rash (defined as confluent lesions) ○ Aged over 50 years <p>OR</p> <ul style="list-style-type: none"> • Diagnosed with shingles within 7 days of rash onset AND ANY of the following: <ul style="list-style-type: none"> ○ Continued vesicle formation ○ Severe pain (consider using a validated pain assessment scale, such as the Visual Analog Scale or Pain Scales produced by the British Pain Society (available in multiple languages)). ○ High risk of severe shingles (e.g. severe atopic dermatitis/eczema, see NICE CKS for further information) ○ Aged 70 years and over <p>IN</p> <ul style="list-style-type: none"> ○ Individuals who are assisted in the taking of their regular medications (e.g. by visiting carers) where adherence with the five time daily regimen for aciclovir would not be achievable OR who are already prescribed 8 or more medicines per day where adherence with the regimen for aciclovir may not be achievable <ul style="list-style-type: none"> • Diagnosed with shingles within 7 days of rash onset in immunosuppressed individuals (for suggested definitions see here) where the rash is NOT widespread OR severe and the individual is systemically well • 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 here). [For equivalent doses in children, see Chapter 6 Green Book] <p>* does not include:</p>

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	<ul style="list-style-type: none"> ○ 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. <p>Additionally, in the event of a supply interruption with aciclovir and it is unable to be procured, the individuals below may be supplied with valaciclovir under this PGD:</p> <ul style="list-style-type: none"> ● Diagnosed with shingles within 72 hours of rash onset AND ANY of the following: <ul style="list-style-type: none"> ○ Non-truncal involvement (e.g. shingles affecting the neck, limbs, or perineum). ○ Moderate or severe pain (consider using a validated pain assessment scale, such as the Visual Analog Scale or Pain Scales produced by the British Pain Society (available in multiple languages)) ○ Moderate or severe rash (defined as confluent lesions) ○ Aged over 50 years <p>OR</p> <ul style="list-style-type: none"> ● Diagnosed with shingles within 7 days of rash onset AND ANY of the following: <ul style="list-style-type: none"> ○ Continued vesicle formation ○ Severe pain (consider using a validated pain assessment scale, such as the Visual Analog Scale or Pain Scales produced by the British Pain Society (available in multiple languages)). ○ High risk of severe shingles (e.g. severe atopic dermatitis/eczema, see NICE CKS for further information) ○ Aged 70 years and over
<p>Criteria for exclusion</p>	<ul style="list-style-type: none"> ● Consent refused and documented in the individual's clinical notes ● Individuals under 18 years of age ● Pregnancy or suspected pregnancy ● Currently breastfeeding with shingles sore(s) on the breast(s) (see Cautions for advice when treating shingles sore(s) not on the breast(s) in breastfeeding individuals) ● 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/μl. ● primary or acquired cellular and combined immune deficiencies – those with lymphopaenia (<1,000 lymphocytes/μl) or with a functional

	<p>lymphocyte disorder</p> <ul style="list-style-type: none"> 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) <p>Individuals on immunosuppressive or immunomodulating therapy including:</p> <ul style="list-style-type: none"> 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) <p>Individuals with chronic immune mediated inflammatory disease who are receiving or have received immunosuppressive therapy</p> <ul style="list-style-type: none"> 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 <p>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.</p> <ul style="list-style-type: none"> Immunosuppressed individuals (see here for definitions of immunosuppressed) where the rash is widespread or severe or the individual is systemically unwell. Known hypersensitivity to valaciclovir or aciclovir 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. Signs or symptoms indicating drug reaction with eosinophilia and systemic symptoms (DRESS) with previous exposure to valaciclovir Individuals, for whatever reason, where medication cannot be started within 72 hours or 7 days of rash onset, whichever is used to determine eligibility for treatment (see criteria for inclusion) Inability to absorb oral medications and or inability to swallow solid
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	<p>oral dosage formulations (i.e. tablets)</p> <ul style="list-style-type: none"> • Current long-term use of oral valaciclovir or aciclovir (e.g. prophylaxis of HSV infection etc.) • Failure to respond to treatment with valaciclovir or aciclovir for this episode of shingles • Shingles rash onset over 7 days ago • Individuals with any underlying neurological condition • Suspected shingles in the ophthalmic distribution of the trigeminal nerve, especially with: <ul style="list-style-type: none"> ○ Hutchinson’s sign (a rash on the tip, side or root of the nose, which is a prognostic factor for subsequent eye inflammation and permanent corneal denervation) OR ○ Visual symptoms OR ○ An unexplained red eye • Serious complications are suspected: <ul style="list-style-type: none"> ○ Meningitis (neck stiffness, photophobia, mottled skin) ○ Encephalitis (disorientation, changes in behaviour) ○ Myelitis (muscle weakness, loss of bladder or bowel control) ○ Facial nerve paralysis (typically unilateral) (Ramsay Hunt syndrome) • Any individual identified with symptoms of severe or life-threatening infection or systemic sepsis: refer urgently via ambulance. • Individuals at risk of dehydration and unable to maintain adequate fluid intake. • Known Chronic Kidney Disease (CKD) stages 3, 4 or 5 (eGFR <60ml/min/1.73m²) • Concurrent use of any interacting medicine as listed in Drug Interactions section of this PGD
<p>Cautions including any relevant action to be taken</p>	<ul style="list-style-type: none"> • Breastfeeding individuals: avoid direct contact between infant and shingles sores. Valaciclovir can be used in breastfeeding individuals; monitor nursing infant for diarrhoea, vomiting, rashes, irritability, lethargy and fever. • Caution should be exercised when supplying valaciclovir tablets to individuals taking the following potentially nephrotoxic medicine(s): <ul style="list-style-type: none"> ○ Individuals known to be taking another medication known to be nephrotoxic (including but not limited to: ACE inhibitors, ARBs, diuretics, NSAIDs, metformin) or known to cause renal impairment (see individual Summary of Product Characteristics or BNF). These individuals should be advised to maintain adequate fluid intake while on treatment with valaciclovir and to avoid dehydration. ○ Individuals known to be taking tenofovir disoproxil fumarate (used alone or in combination) for the treatment of hepatitis B, HIV pre-exposure prophylaxis (PrEP) or post exposure prophylaxis (PEP) should contact the provider of these medications to discuss the need for additional monitoring, due to the potential increased risk of renal impairment with concomitant nephrotoxic drugs. Valaciclovir may be supplied under this PGD.

	<ul style="list-style-type: none"> • Caution should be exercised when supplying valaciclovir tablets to individuals who should avoid the following excipients: <ul style="list-style-type: none"> ○ 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.
<p>Specific information for suspected infection to be provided</p>	<ul style="list-style-type: none"> • Provide the British Association of Dermatologists (BAD) patient information leaflet on shingles (herpes zoster infection). • Provide individual with advice on pain management: recommend to all individuals with mild pain, where appropriate, a trial of paracetamol, alone or combination with codeine or a nonsteroidal anti-inflammatory drug (NSAID), such as ibuprofen (over the counter). • Signpost eligible individuals to information and advice about receiving the shingles vaccine advising they discuss vaccination with their GP practice after they have recovered from this episode of shingles.
<p>Action to be taken if the individual is excluded</p>	<ul style="list-style-type: none"> • Record reasons for exclusion in the appropriate clinical record <p>Individuals where treatment is not indicated:</p> <ul style="list-style-type: none"> • Advise individual/carer/parent/guardian of alternative non antiviral treatment if antiviral not indicated and provide the British Association of Dermatologists (BAD) patient information leaflet on shingles (herpes zoster infection) and safety netting advice. • Refer the individual to the NHS website containing patient information on shingles. • Provide patient with advice on pain management: recommend to all individuals with mild pain, where appropriate, a trial of paracetamol, alone or combination with codeine or a nonsteroidal anti-inflammatory drug (NSAID), such as ibuprofen (over the counter). <p>Refer urgently to a prescriber for further assessment if:</p> <ul style="list-style-type: none"> • Known or suspected pregnancy • Pain inadequately controlled with over the counter analgesia • Systemically unwell, but not showing signs or symptoms of sepsis • Individuals where treatment under this PGD is not indicated/permitted but dermatological symptoms are present and require further assessment <p>Refer urgently to A&E for further assessment if:</p> <ul style="list-style-type: none"> • Individual is severely immunosuppressed • Individual is immunosuppressed and rash is widespread or severe or individual is systemically unwell

	<ul style="list-style-type: none"> • Serious complications such as meningitis, encephalitis, myelitis or facial nerve paralysis are suspected • Shingles in the ophthalmic distribution of the trigeminal nerve: <ul style="list-style-type: none"> ○ Hutchinson’s sign (rash on the tip, side or root on the nose) ○ Visual symptoms ○ Unexplained red eye <p>If sepsis or serious complications are suspected refer the individual urgently to A&E</p>
Action to be taken if the individual/carer/parent/guardian declines treatment	<ul style="list-style-type: none"> • Document advice given • Provide safety netting advice and advise individual/carer/parent/guardian of alternative treatment available using the British Association of Dermatologists (BAD) patient information leaflet on shingles (herpes zoster infection) • Signpost the patient to the NHS website containing patient information on shingles. • Provide individual with advice on pain management • Refer to a prescriber if appropriate
Arrangements for referral for medical advice	Refer to a prescriber if antiviral appropriate but falls outside of this PGD.

Description of treatment

Name, strength & formulation of drug	Valaciclovir 500mg tablets
Legal category	POM
Route / method of administration	Orally, tablets swallowed whole with water
Off-label use	<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 a 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 or manufacturer 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	1g three times a day

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administration	
Duration of treatment	7 days Treatment should be started immediately and 7 days of treatment completed
Quantity to be supplied	Adults: Appropriately labelled pack of 42 x 500mg tablets
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, valaciclovir must not be supplied under this PGD and the individual referred to a prescriber: <ul style="list-style-type: none"> • Ciclosporin, tacrolimus or mycophenolate • Aminophylline or theophylline <p>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>
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 <p>The following side effects are listed in the product SPC or BNF as common with valaciclovir (but may not reflect all reported side effects):</p> <ul style="list-style-type: none"> • Diarrhoea • Vomiting and nausea • Abdominal pain • Headache • Dizziness • Fever • Fatigue • Skin rashes/reactions (including photosensitivity and urticaria) <p>Although rare, drug reaction with eosinophilia and systemic symptoms (DRESS) has been reported in patients taking valaciclovir. DRESS is a specific, severe, unexpected reaction to a medicine, which affects several organ systems at the same time. It typically causes a combination of:</p> <ul style="list-style-type: none"> • High fever • Morbilliform eruption • Haematological abnormalities • Lymphadenopathy • Inflammation of one or more internal organs. <p>Onset is typically 2-6 weeks after first exposure (reduced to days after subsequent exposure). If signs and symptoms suggestive of DRESS</p>

	<p>appear, valaciclovir should be withdrawn immediately and the patient referred to a prescriber. Valaciclovir must not be restarted in these individuals at any time.</p> <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>Management of and reporting procedure for adverse reactions</p>	<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 via organisation incident policy. • It is considered good practice to notify the individual's GP in the event of an adverse reaction.
<p>Written information to be given to individual/carer/parent/guardian</p>	<ul style="list-style-type: none"> • Provide marketing authorisation holder's patient information leaflet (PIL) provided with the product. • Provide the British Association of Dermatologists (BAD) patient information leaflet on shingles (herpes zoster infection) • The NHS website has patient information on shingles. • Give any additional information in accordance with the service specification.
<p>Individual advice / follow up treatment</p>	<ul style="list-style-type: none"> • Explain the dose, frequency and method of administration. • The individual/carer/parent/guardian should be advised to read the PIL. • Inform the individual/carer/parent/guardian of possible side effects and their management. • Advise individual/carer/parent/guardian to take the medication at regular intervals and to finish the course even if symptoms improve. • Advise individual/carer/parent/guardian that if a dose is missed it should be taken as soon as it is remembered unless it is nearly time for the next dose when it should be omitted. Advise then to take the next dose at the correct time. • Shingles usually resolves within 4 weeks – advise individual to seek medical advice if symptoms have not resolved within this time. • Advise individual/carer/parent/guardian to seek immediate medical attention if the individual is immunosuppressed and becomes systemically unwell or the rash becomes widespread or severe. • Advise individual/carer/parent/guardian to seek medical advice if symptoms worsen rapidly or significantly at any time or do not improve after completion of treatment course. • Advise individual/carer/parent/guardian to seek immediate medical

	<p>attention (by calling 999 or going to A&E) if the individual develops signs or symptoms of sepsis.</p> <ul style="list-style-type: none"> • Advise individual/carer/parent/guardian to seek medical advice if new vesicles are forming after 7 days of antiviral treatment, or healing is delayed. • Advise individual/carer/parent/guardian to seek medical advice if pain is inadequately controlled by over-the-counter analgesia. • 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. • 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. • Advise individual/carer/parent/guardian to ensure the individual maintains adequate hydration particularly in the elderly to prevent renal impairment • Explain that only a person who has not had chickenpox or the varicella vaccine can catch chickenpox from a person with shingles. The person with shingles is infectious until all the vesicles have crusted over (usually 5–7 days after rash onset). • Advise individuals with shingles to: <ul style="list-style-type: none"> ○ Avoid contact with individuals who have not had chickenpox, particularly pregnant individuals, immunosuppressed individuals, and babies younger than 1 month of age. ○ Avoid sharing clothes and towels. ○ Wash their hands often. ○ Wear loose-fitting clothes to reduce irritation. ○ Cover lesions that are not under clothes while the rash is still weeping. ○ Avoid use of topical creams and adhesive dressings, as they can cause irritation and delay rash healing. ○ Keep the rash clean and dry to reduce the risk of bacterial superinfection. They should seek medical advice if there is an increase in temperature, as this may indicate bacterial infection. ○ Avoid work, school, or day care if the rash is weeping and cannot be covered. If the lesions have dried or the rash is covered, avoidance of these activities is not necessary.
Records	<p>Appropriate records must include the following:</p> <ul style="list-style-type: none"> • 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)

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- 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 (accessed last accessed November 2023)</p>	<ul style="list-style-type: none"> • DermNet. Drug hypersensitivity syndrome. https://dermnetnz.org/topics/drug-hypersensitivity-syndrome • British Association of Dermatologists (BAD) Shingles (herpes zoster infection) patient information leaflet (May 2020) https://www.bad.org.uk/pils/shingles-herpes-zoster/ • Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.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 • NHS website “Shingles” https://www.nhs.uk/conditions/shingles/. • NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2 • NICE Clinical Knowledge Summaries (CKS) Shingles https://cks.nice.org.uk/topics/shingles/ • NICE summary of antimicrobial prescribing guidance – managing common infections (Dec 2022) https://www.bnf.org/wp-content/uploads/2023/02/summary-antimicrobial-prescribing-guidance_feb-23_FINAL.pdf • UK Sepsis Trust. Sepsis e-learning resources. https://sepsistrust.org/professional-resources/sepsis-e-learning/ • Shingles Support Society “Frequently Asked Questions About Shingles” https://shinglessupport.org.uk/frequently-asked-questions-about-shingles/ • Shingles Support Society “Frequently Asked Questions About Postherpetic neuralgia (PHN)” https://shinglessupport.org.uk/frequently-asked-questions-about-post-herpetic-neuralgia-phn/. • Stockley’s Drug Interaction Checker https://www.medicinescomplete.com
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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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