Brighton and Sussex University Hospitals NHS Trust

This Patient Group Direction (PGD) must only be used by registered health 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

For the supply[1] of

Flamazine 1% (Silver Sulfadiazine) cream

by Therapy Radiographers registered by the Health & Care Professions Council (HCPC)

to Cancer patients undergoing Radiotherapy planning CT scans, External Beam Radiotherapy treatment or Brachytherapy radiotherapy treatment to the pelvis

in the BSUH Radiotherapy Department at the **Sussex Cancer Centre** –

Royal Sussex County Hospital (RSCH)

Preston Park Radiotherapy Centre (PPRC)

Eastbourne Radiotherapy Unit (ERTU)

Change history

Version number	Change details	Date
1	New PGD	09/2017
2	Word change from 'post' to 'completion' and 'undergoing to completion' Added – patients who are still receiving RT or chemo rad	09/2017
3	Size change from 20g to 50g	10/2017
4	New template	10/2020

PGD development

Name	Job title and organisation	Signature	Date
Lead author : Hetal Raval	Lead Review Radiographer, BSUH	QPulse - Electronic Signature	19.01.21
Lead Doctor Kate Lankester	Consultant Clinical Oncologist	QPulse - Electronic Signature	24.12.20
Lead pharmacist Summer Ibrahim	Lead Pharmacist for Cancer Services and R&D	Email Approval	08.01.21
Lead Clinician for area Ashok Nikapota	Consultant Clinical Oncologist	QPulse - Electronic Signature	05.01.21
Representative of other professional group using PGD (User review) Kate McBurney	Operational Lead Radiographer	QPulse - Electronic Signature	06.01.21

Organisational authorisations

Brighton & Sussex University Hospitals NHS Trust authorises this PGD for use by the services or providers listed below:
Radiotherapy Services BSUH
Limitations to authorisation
Radiographers with current HCPC registration only **Must be a permanent member of staff at BSUH**

Name	Signature & Name	Date
Chair of PGD Group	Via email J. Pendlebury	31/3/21
Chief Pharmacist	Via email M.Cross	May 2021
Medicines Governance Group chair	Via email M.Okorie	May 2021

Local enquiries regarding the use of this PGD may be directed to Bsuh.pgdgroup@nhs.net or PGD group chair.

Appendix 1 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD.

Approved date May 2021 Expiry date May 2023

Training and competency of registered health professionals

	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	Qualified Therapy Radiographers with HCPC registration and a minimum of 12 months post qualification clinical experience.
Additional requirements	**THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.** **The individual practitioner is required to have a working knowledge of adverse reactions to the medication used with the PGD and how to identify drug interactions.**
Initial training	Register and complete PGD training module (certificate can be printed out as evidence) https://portal.e-lfh.org.uk/ (3 yearly) Has under taken local PGD training (located with Q-Pulse – documentation management system) • PGD training for Radiographers (ONC-TR-2141) *training document* • PGD documentation process (ONC-WI-4332) *work instruction* • Specific training for this PGD (ONC-EXT-0425) *External document* Other required training includes: BSUH Trust approved IRIS training including Adult BLS and anaphylaxis
Competency assessment	Entitled trainers for this PGD (inclusive of the author) are responsible for ensuring the • PGD competency assessment • Agreement to practice (Appendix 1) • PGD – *Quality record is* updated in Q-Pulse All Documentation is located within Q-Pulse – documentation management system: **C:\Users\Public\Desktop\Q-Pulse.lnk** Entitled trainer assesses via scenario based questions.
Continued training requirements	Complete NICE Competency PGD Framework PGD e-learning 3 yearly Up to date with mandatory training for Adult basic life support and anaphylaxis training. Maintain knowledge and skills within specialist area Completion and submission of continuous practitioner development (CPD) as required by the HCPC

Clinical condition

Clinical condition or situation to which this PGD applies	Patients undergoing radiotherapy or chemo-radiation to any area in the body - for the symptomatic treatment of acute skin reaction (RTOG : 2b and above) caused by the radiotherapy RTOG – see key references
Inclusion criteria	• Patient have been referred and consented for radiotherapy treatment by entitled practitioners under Ionising Radiation (medical exposure) Regulations IR(ME)R and have completed their course of radiotherapy. • Patients who are 18 years of age or greater
Exclusion criteria	• Patients who are 17 years of age or younger • Patients who have not completed their radiotherapy treatment • Patients with known allergies to silver or sensitive to sulfonamides • Patients with known or suspected pregnancy or breast feeding • Patients with renal and hepatic impairment • Patients with G6PD Deficiency
Cautions (including any relevant action to be taken)	Check concurrent patient medication for potential adverse drug reactions and once identified: • **Patient to be reminded to read the accompanying manufacturer's printed information.** • **Patient to be given the written instructions and the pack described in the written instructions.ONC-PI-56.** As large amounts may interfere with: oral contraceptives, anesthetics, anticoagulants, diabetic and epileptic medication, anti-malaria, cyclosporine and cytotoxic medication. Check pregnancy status if it is possible for the patient to child bear within age 12-60yrs.
Arrangements for referral for medical advice	Refer to Consultant Clinical Oncologist or on call registrar.
Action to be taken if patient excluded	Refer patient to duty doctor/prescriber for alternative solution/ action plan Document actions in Mosaiq (oncology information management system) in the notes section of the patient's electronic record.
Action to be taken if patient declines treatment	Advise patient of alternatives (dressings), risks and potential outcomes which will affect their treatment if they do not administer

	this medication. Advise skin reaction increases with time and dose received; and continue for up to two weeks after completion of treatment. Inform the patients Oncologist

Details of the medicine

Name, form and strength of medicine *Include ▼for black triangle medicines*	Flamazine Cream (Silver Sulfadiazine 1%) 50 g tubes
Legal category	*POM*
Indicate any off-label use (if relevant)	*N/A*
Route/method of administration	Topical antibiotic, apply to broken skin only a layer of 3 to 5 mm.
Dose and frequency	With clean hands/ or a glove, apply a layer of 3 to 5 mm of cream Use it once a day or a maximum of twice a day as instructed.
Quantity to be supplied	To supply up to 4 x 50 mg tubes depending on the skin area that presents with moist desquamation on completion of Radiotherapy. The contents of one container is for the treatment of one person. Tubes of Flamazine should be discarded 7 days after opening.
Maximum or minimum treatment period	Use cream until skin healed or for a maximum treatment period of 2 weeks.
Adverse effects	• Itching (pruritus) • Burning sensation • Rash • Leucopaenia (when used on large areas of skin – not common in radiotherapy) A detailed list of adverse reactions is available in the SPC for each medicine, which are available from the electronic MHRA website: https://mhraproducts4853.blob.core.windows.net/docs/88e19b52e3743568c85ef9facd83aa3b9f28c29e BNF/C also has information on adverse effects. https://www.medicinescomplete.com/#/content/bnf/_457990655?hspl=flamazine#content%2Fbnf%2F_457990655%23pot-indicationsDose
Drug interactions	A detailed list of drug interactions is available in the SPC (summary of product which are available from the electronic MHRA website: https://mhraproducts4853.blob.core.windows.net/docs/88e19b52e3743568c85ef9facd83aa3b9f28c29e BNF/C also has drug interaction information https://www.medicinescomplete.com/#/content/bnf/_457990655?hspl=flamazine#content%2Fbnf%2F_457990655%23pot-indicationsDose
Supplies	From Internal BSUH Pharmacy

Storage	Flamazine should be stored below 25°C. Protect from light as per the 'Safe and Secure Handling of Medicines' policy (BSUH intra net – micro guide)
Reporting procedure of adverse reactions	Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk
Special considerations / additional information	Patient information leaflet (PIL) – manufactures information supplied with the medicine. https://products.mhra.gov.uk/search/?search=flamazine&page=1 See below in section: **Written information to be given to patient or carer**
Records to be kept	Record: *Using Mosaiq within the PGD specific Assessment record* • that valid informed consent was given; • name of individual, address, date of birth and GP with whom the individual is registered • Drug history for patient including medical history • name of HCP • name of medication • date of administration • dose, form and route of administration • quantity administered • batch number and expiry date (if required) • advice given • details of any adverse drug reactions and actions taken • supplied via PGD **A report of associated records of all individuals receiving treatment under this PGD is kept for audit purposes in accordance with local policy and /or the patients should be identifiable in a timely manner for audit purposes.**
Written information to be given to patient or carer	Local Information leaflet: How to use Flamazine (ONC-PI-56)
Follow-up advice to be given to patient or carer	***Information leaflets given pre and post radiotherapy have all relevant contact details with in them.*** ***During:*** Patients are encouraged to discuss any issues/ concerns with radiographers when they attend daily for their course of radiotherapy treatment. ***Post radiotherapy:*** for advice during the working week: patient can call the specialised Review Radiographer. The patient will have a follow up appointment arranged with an Oncologist approximately 4 to 6 weeks after treatment is completed. ***Out of hours:*** patient to contact GP or 111 or attend A&E

Audit

Plan for audit, It is essential for PGD renewal that audits have occurred**.**	Incorporate in Radiotherapy Service audit plan
Frequency	Every 2 years
Nominated lead to manage audit	*Hetal Raval* - Lead Review Radiographer, BSUH

Key references

Key references	
The Society and College of Radiographers Practice Guideline Document Radiation Dermatitis Guidelines for Radiotherapy Healthcare Professionals Second revised edition April 2020 Review date: 2025 ISBN: 978-1-909802-49-0	Skin care for Radiotherapy patients – using RTOG criteria
COX, J., STETZ, J. and PAJAK, T. 1995. Toxicity criteria of the Radiation Therapy Oncology Group (RTOG) and the European Organisation for Research and Treatment of Cancer (EORTC). *International Journal of Radiation Oncology • Biology • Physics.* 31(5): 1341–6.	RTOG criteria still in use as best practice

Appendix 1 Health professionals' agreement to practise

PGD Title **Flamazine 1% (Silver Sulfadiazine) cream**

Practitioner, 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 practice 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 of health professional	Role	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Brighton & Sussex University Hospitals NHS Trust for the above named health care professionals who have signed the PGD to work under it.

Name	Role	Signature	Date