# Intralesional Injection of Bleomycin for the Treatment of Vascular Anomalies

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**Document control information** *(Published as separate document - Please contact the Document Control Administrator – john.taylor@srft.nhs.uk)*

- Document Control
- Policy Implementation Plan
- Monitoring and Review
- Endorsement
- Equality analysis

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**Salford Royal NHS Foundation Trust**

**University Teaching Trust**

**safe clean personal**
Who should read this document?

- All Consultants and Specialist Registrars who prescribe and administer Bleomycin for the treatment of vascular anomalies.
- All Pharmacists who are responsible for checking and dispensing prescriptions for treatment of vascular anomalies.
- All nurses who work in angiography where bleomycin for the treatment of vascular anomalies is administered.

Key Messages

Salford Royal Hospital NHS Foundation Trust (SRFT) aims to eliminate preventable harm from cytotoxic chemotherapy through the implementation of systematic arrangements for the safe management of cytotoxic chemotherapy.

This document outlines the procedure for the prescribing, preparation and administration of bleomycin for the treatment of vascular anomalies to patients at SRFT.

This policy has been written and agreed by the Chemotherapy Service Group (a sub group of the Medicines Management Group) and should be followed by medical, nursing, pharmacy and all other staff who are involved in the care of these patients receiving bleomycin.

The safe prescribing, preparation and administration of all cytotoxic drugs is the responsibility of medical, nursing and pharmacy staff. Cytotoxic drugs have a narrow therapeutic index requiring extreme care to protect patients from receiving the incorrect drug, dosage, formulation or route of administration.

Special handling precautions are necessary for cytotoxic drugs as they are irritant and potentially carcinogenic and/or teratogenic. They may be absorbed through the skin, lungs and/or gastrointestinal tract and therefore pose specific significant risks to staff.

Pregnant staff should avoid exposure to cytotoxic chemotherapy drugs. All females of child bearing age should be informed of the reproductive hazard. Individual members of staff should discuss concerns with their line manager and an individual risk assessment carried out.

Background & Scope

This policy must be read in conjunction with the Trust Medicines Policy and cytotoxic policy.

All patients who require Intralesional Bleomycin for a venous/lymphatic malformation will be treated in accordance with this protocol. Any deviations will require an “off protocol” variance form to be completed (forms available from pharmacy) prior to a supply of therapy.
INFORMED CONSENT must be obtained and documented before prescribing intralosomal bleomycin due to the nature of the side effects

What is new in this version?

Change of authors
Confirmation of dose and strength to be used
Referenced to cytotoxic chemotherapy policy 200TD( C ) 46 where appropriate

Policy/ Guideline/ Protocol

Therapeutic Indications

Intralosomal bleomycin is not currently licensed for intratumoral injection, but over the past decade a few medical centres have reported excellent results in the treatment of venous/lymphatic malformations by direct intralosomal injection of bleomycin. The number of centres using this technique continues to increase especially in children with reports of very good results with no significant complications.

Description

Bleomycin is an antibiotic derivative with cytostatic properties. Its antimitotic activity works by breaking the DNA strands mainly in the M and G3 phases of the cell cycle. The sclerosing effect of bleomycin on the vascular endothelium was first used to treat lymphatic malformations (LM) by intralosomal injection in 1977. A review of 435 patients treated using this technique by 2004 demonstrated a variety of results according to diagnosis. The complete or near complete obliteration rates for LM and VM (venous malformations) were in the range of 80-90% comparing favourably with outcomes using other sclerosants such as ethanol. The major advantage of intralosomal bleomycin in VM being the absence of recurrence. Traditional scleropathy with currently used sclerosants though effective is not usually curative and may require sequential procedures to facilitate the desired result.

Dosage

Bleomycin powder is reconstituted with 15mls of 0.9% Sodium chloride creating a solution of 1mg/ml. In adults a dose of 1-15mg will be injected at each treatment session. A single dose should not exceed 15mgs.

Adverse Effects

The risks associated with the administration of this drug are:

- To patients - intralosomal injection of bleomycin is known to give rise to localised swelling, inflammation and possibly fever for a few days. Other reported complications include flu-like symptoms, skin ulceration, cellulitis and a very small percentage of patients reported partial temporary hair loss. There may be transient or permanent

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skin discolouration especially where surgical tape or electrodes are placed during anaesthesia.

Bleomycin is also associated with pulmonary fibrosis, but this is usually linked to an accumulated dose (of greater than 250mgs administered systemically via intravenous infusion), older age, abnormal renal function and the concurrent use of other cytotoxic drugs. The treatment of VM with intralesional bleomycin requires small doses and the cumulated dose is carefully monitored. There have been no episodes of pulmonary fibrosis in any of the 400 patients monitored in published reports.

- To staff and carers – exposure to Cytotoxic material. This might occur from incorrect handling of the drug or by direct contact with the injected area.

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<th>Eligibility Criteria</th>
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<td>Patient eligibility for intralesional bleomycin is determined by the following criteria:</td>
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<td>• Adult patients with venous/lymphatic malformations.</td>
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<th>Contra indications</th>
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<tr>
<td>Intralesional bleomycin should not be used in patients in the following circumstances:</td>
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<tr>
<td>• If the patient does not meet the eligibility criteria</td>
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Pregnancy
Intralesional bleomycin should not normally be administered to pregnant women, and women of childbearing age should be advised to avoid pregnancy whilst receiving

Lactation
It is not known if the components of Bleomycin are excreted in breast milk – therefore because of the potential adverse reactions of Bleomycin in nursing infants, breastfeeding is contra-indicated.

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<th>Prescribing</th>
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<td>All prescriptions are to be presented to the inpatient pharmacy on the ‘Bleomycin for Vascular Anomalies’ specific prescription chart with the relevant patient and prescriber details as per local Trust policy</td>
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<th>Therapeutic Procedure</th>
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<td>Bleomycin injections are almost always painful and are given under general anaesthesia in the interventional suite, angiography rooms Monday to Friday 9am to 5pm. A series of injections is usually required (three to four in the...</td>
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published literature), this may vary according to the size of the lesion. The period of time between treatments is usually 3-4 weeks.

### Disposal and Wastage

Each management area involved in this patient pathway must ensure all staff are aware of the Health & Safety issues associated with the administration of intralesional bleomycin to patients.

Staff must be provided with appropriate personal protective equipment for the handling of cytotoxic drugs and contaminated materials.

At conclusion of the procedure only syringes and needles contaminated with bleomycin are to be disposed of into a designated yellow sharps bin with a purple lid (cytotoxic).

All personal protective equipment which has been or may have been exposed to cytotoxic contamination should be bagged for incineration and labelled as cytotoxic waste.

The cytotoxic spillage policy must be readily available in each management area and be followed in the event of contamination.

Please refer to the cytotoxic policy for further details.

### Standards

National Cancer Peer Review Programme, Manual for Cancer Services: Chemotherapy Measures version 1.0 April 2014

### Explanation of terms & Definitions

Terms explained in document

### References and Supporting Documents


http://www.dermnetnz.org/topics/bleomycin/

Roles and responsibilities

The Chief Executive is accountable to the Trust Board for ensuring that:

- Policy is developed and implemented across the Trust
- Implementation is monitored and that any deficiencies are brought to the attention of the Trust Board

Angiography manager will be responsible for:

- Keep under review current risk assessment, control measures, procedures and training within their areas to ensure where deficiencies are identified, recommendations and actions plans are developed.
- Ensure adequate provision of training and support to staff in relation to the requirements of this policy and the administration of intralional bleomycin and care of patients receiving this.
- Ensure all deviations from policy are identified via the adverse incident system.

Pharmacy is responsible for:

- Ensuring that all prescriptions clinically checked for intralional bleomycin are in accordance with the policy.
- Ensure that parenteral chemotherapy is prepared in a safe manner.