Ballarat Health Services

DRUG GUIDELINE

UROKINASE – Thrombolysis in Cardiovascular Unit (CVU) and Intensive Care Unit (ICU)

HIGH RISK MEDICATION

SCOPE (Area): **FOR USE IN:** CVU, ICU
EXCLUSIONS: Paediatrics (seek Paediatrician advice), all other areas
SCOPE (Staff): Medical, Nursing and Pharmacy

Urokinase is only available via the Special Access Scheme (SAS), a Category A form must be completed for all patients. See https://sas.tga.gov.au/ for more information.

BRAND NAMES
Syner-KINASE.
Brands may change on short notice (some brands are stored in the fridge).

PHARMACOLOGY AND PHARMACOKINETICS
Urokinase is a thrombolytic agent that binds to the fibrin component of the thrombus and converts thrombus bound plasminogen to plasmin; this degrades the fibrin matrix of the thrombus.
Half-life up to 20 minutes; longer in patients with hepatic or renal dysfunction. Effects may persist for a few hours after urokinase is ceased.

INDICATIONS
- Catheter-directed thrombolysis for peripheral arterial thrombus in critical limb ischaemia.
- **For thrombosed arteriovenous fistula (AVF) see Appendix 1.**

CONTRAINDICATIONS
Absolute
- Ongoing bleeding after failed haemostasis or active bleeding not viable to treat.
- Intracranial haemorrhage.
- Presence or development of compartment syndrome.
- Severe limb ischaemia, which in the judgement of the treating team requires immediate operative intervention.

Relative
- Established cerebrovascular event (including transient ischaemic attack within 2 months).
- Major nonvascular surgery or trauma within last 10 days.
- Uncontrolled hypertension: greater than 180 mm Hg systolic or 110 mm Hg diastolic blood pressure.
- Puncture of non-compressible vessel.
- Intracranial tumour.
- Intracranial trauma within the last 3 months.
- Recent internal or non-compressible haemorrhage.
- Recent eye surgery.
- Neurosurgery within the last 3 months.

- Severe contrast allergy or hypersensitivity.
- GI bleeding within the last 10 days.
- Hepatic failure, particularly those with coagulopathy.
- Bacterial endocarditis.

PRECAUTIONS

- **Intrathecal or epidural analgesia or anaesthesia, or lumbar puncture** – risk of epidural haematoma which can cause paralysis, seek specialist advice before proceeding for patients who have recently had neuraxial procedures performed, or require neuraxial procedures after thrombolysis. See CPP0729 Perioperative Management of Anticoagulant & Antiplatelet Agents.
- Hypersensitivity to urokinase – review extent of reaction.
- INR greater than 2 or platelets less than 50 $x10^9$/L – report to the Interventional Radiologist.

PREGNANCY AND BREASTFEEDING

Pregnancy and first 10 days postpartum are a relative contraindication. Limited information available in breastfeeding, manufacturer recommends avoiding breastfeeding during treatment with urokinase. Seek specialist advice before prescribing, information may update regularly.

DRUG INTERACTIONS

The following medications given in combination with urokinase increase the risk of bleeding. Monitor closely for signs of bleeding. This risk may continue for several days after discontinuation of agent.

Other thrombolytics	alteplase, tenecteplase.
Heparin and low molecular weight heparins	dalteparin, danaparoid, enoxaparin, heparin, nadroparin.
Direct thrombin inhibitors	argatroban, bivalirudin, dabigatran
Vitamin K antagonists	warfarin.
Factor Xa inhibitors	apixaban, fondaparinux, rivaroxaban.
Glycoprotein IIb/IIIa inhibitors	eptifibatide, tirofiban.
Non-steroidal anti-inflammatory agents (NSAIDs)	Aspirin (low dose OK), diclofenac, ibuprofen, indometacin, ketoprofen, ketorolac, mefenamic acid, naproxen, piroxicam. Note: Selective NSAIDs (celecoxib, etoricoxib, meloxicam, parecoxib) do not directly affect clotting, but increase the risk of gastrointestinal bleeding
Selective serotonin reuptake inhibitors	citalopram, dapoxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline.
Serotonin and Noradrenaline Reuptake Inhibitors	desvenlafaxine, duloxetine, venlafaxine
Prostacyclin analogues	epoprostenol, iloprost.
Other	anagrelide, clopidogrel, dipyridamole, prasugrel, protein C concentrate (human), ticagrelor.
Herbal medications	bilberry, bromelain, embilica, garlic, ginger, ginkgo biloba, ginseng (american), ginseng (panax), ginseng (siberian), policosanol.

- **Angiotensin Converting Enzyme (ACE) inhibitors –** may increase the risk of angioedema.
- **Tranexamic acid –** decreased effectiveness of each agent.

DOSAGE AND ADMINISTRATION

Resuscitation equipment must be available in case anaphylaxis occurs.
For administration only:

- **in Cardiovascular Unit (CVU) or Intensive Care Unit (ICU)**

Only to be prescribed by an Interventional Radiologist.

Two IV access points are required prior to commencing urokinase for the and for blood sampling.

Pre-thrombolysis bloods to be taken:

- **Blood clotting profile: including activated partial thromboplastin time (APTT), INR & fibrinogen concentration**
- **U&Es, FBE, LFTs, and Group and Hold should be determined from the current admission**
- **INR greater than 2, or platelets less than 50 x10^9/L, must be reported to the Interventional Radiologist.**

Urokinase important information:

- **Administered via special multi-side hole thrombolysis intra-arterial catheter lying near or within the thrombus only. Only urokinase, heparin or sodium chloride 0.9% may be administered through this line.**
- **The urokinase syringe and line must be clearly labelled as intra-arterial.**
- **Urokinase infusion is administered for 12 hours, until re-angiogram or as determined by the Interventional Radiologist.**
- **Urokinase intra-arterial boluses are recorded on the Interventional Radiology report AND Once Only Orders section of the NSMC MR/700.2 see Appendix 2 for example order.**
- **Urokinase intra-arterial infusions are ordered on a modified Intravenous Order chart MR/645.0 with an intra-arterial route sticker or highlighting to clearly show the route is intra-arterial, see Appendix 2 for example order.**

A maximum of 12 hours duration of urokinase is stocked on CVU imprest. Urokinase is only available via the SAS, a form must be filled out for each patient for the maximum amount of urokinase that may be required. Contact Pharmacy as soon as possible to arrange ongoing urokinase supply if over 12 hours duration is planned. If out of hours obtain extra supply from the on-call Pharmacist via the Patient Flow Coordinator.

See Appendix 2 for detailed information regarding setup, equipment and procedures.

Reconstitution:

Reconstitution diluent and volume vary according to brand. Check product information and/or Australian Injectable Drugs Handbook (AIDH) carefully.

Prepare reconstituted solution to a final concentration of 50,000 units/mL

- Reconstitute urokinase 100,000 unit vials with a total of 2 mL diluent.
- Reconstitute Syner-KINASE® 500,000 units vials with 5 mL sodium chloride 0.9% and then further dilute to 10 mL. For reconstitution of other brands, see the AIDH.
- To prevent froth formation, do not shake the vial and direct the diluent to the wall of the vial. The reconstituted solution should be clear and colourless.

ALL DOSES REQUIRE INDEPENDENT DOUBLE CHECKING

PERIPHERAL ARTERIAL THROMBUS:

The Interventional Radiologist determines whether the patient requires:
- A urokinase bolus only
- A urokinase 12-hour infusion as well, depending on the effectiveness of the bolus.

BOLUS:

Boluses are administered by the Interventional Radiologist only.

Dose: 2,000 units/kg intra-arterially, to a maximum of 200,000 units.

Preparation (see Table 1 below):
- Reconstitute as per instructions above to a final concentration of 50,000 units/mL.
- Draw up urokinase 50,000 units/mL solution corresponding to a dose of 2,000 units/kg.
- Dilute urokinase further with sodium chloride 0.9% to a **final volume of 4 mL** (if required).

Administration: give 4 mL by slow intra-arterial hand injection OR infuse 4 mL intra-arterially via Alaris® Syringe Module (Basic Infusion) over 20 minutes (12 mL/hr).

Table 1: UROKINASE BOLUS
Combine required volume of urokinase 50,000 units/mL solution with sodium chloride 0.9% to a final volume of 4 mL

Patient weight	Dose of urokinase (2,000 units/kg)	Volume of reconstituted urokinase (50,000 units/mL)	Volume of sodium chloride 0.9%
40 kg	80,000 units	1.6 mL	2.4 mL
50 kg	100,000 units	2 mL	2 mL
60 kg	120,000 units	2.4 mL	1.6 mL
70 kg	140,000 units	2.8 mL	1.2 mL
80 kg	160,000 units	3.2 mL	0.8 mL
90 kg	180,000 units	3.6 mL	0.4 mL
100 kg or more **MAXIMUM**	200,000 units	4 mL	0 mL
FINAL VOLUME: 4 mL			

12-HOUR INFUSION (if required):

Dosing is varied and determined by the Interventional Radiologist, and may vary from those listed.

Usual dose: 2,000 units/kg/hr for a 12-hour infusion, to a maximum of 200,000 units/hr (weight capped at 100 kg).

Preparation (see Table 2 below):

- Calculate total dose of urokinase required for the 12-hour infusion (i.e. 12 hr x weight (kg) x 2,000 units/kg/hr).
- Reconstitute as per instructions above to a final concentration of 50,000 units/mL.
- Draw up urokinase 50,000 units/mL reconstituted solution corresponding to the total dose.
- Dilute the urokinase further with sodium chloride 0.9% to a **final volume of 48 mL** (if required).

Administration: infuse 48 mL intra-arterially over 12 hours (4 mL/hr) via Alaris® Syringe Module (Basic Infusion).

- **Once urokinase is ceased maintain sheath patency with an intra-arterial infusion of 20 mL/hr sodium chloride 0.9% until sheath removal.**

Table 2: UROKINASE 12-HOUR INFUSION
Combine required volume of urokinase 50,000 units/mL solution with sodium chloride 0.9% to a final volume of 48 mL

Patient weight	Total dose of urokinase (12 hr x weight (kg) x 2,000 units/kg/hr)	Volume of reconstituted urokinase (50,000 units/mL)	Volume of sodium chloride 0.9%
40 kg	960,000 units	19.2 mL	28.8 mL
50 kg	1,200,000 units	24 mL	24 mL
60 kg	1,440,000 units	28.8 mL	19.2 mL
70 kg	1,680,000 units	33.6 mL	14.4 mL
80 kg	1,920,000 units	38.4 mL	9.6 mL
90 kg	2,160,000 units	43.2 mL	4.8 mL
100 kg or more **MAXIMUM**	2,400,000 units	48 mL	0 mL
FINAL VOLUME: 48 mL			

HEPARIN INFUSION

- A heparin 5,000 unit **intra-arterial OR intravenous** bolus is given by Interventional Radiologist in Catheterisation lab and recorded on the Interventional Radiology report AND Once Only Orders section of the National Standard Medication Chart (NSMC) MR/700.2.
- After the urokinase bolus is given, a heparin **intravenous** infusion at a rate of 500 units/hr is required. Prescribe on the Heparin Intravenous Infusion Chart MR/700.3 without further bolus.
- Target APTT is 50 to 70. Check APTT 6 hourly until patient is reassessed in Catheterisation lab (usually 12 hours post procedure).
- Consult ICU medical staff or Interventional Radiologist for heparin infusion dosage adjustment given there is a non-standard target APTT of 50 to 70.
- The duration of heparin infusion after urokinase is ceased is decided by the Interventional Radiologist on a case by case basis.

General Administration Information

- **Infusion pump:** BD Alaris® Syringe Module (via Basic Infusion)
- **Routes of administration:**

Intra-arterial:	Yes (injection and infusion)
IV injection:	No
IV intermittent infusion:	Not at GH-B
IV continuous infusion:	Not at GH-B
IM injection:	No
Subcut injection:	No

- **Compatible/incompatible IV drugs/fluids:**
  Consult the Australian Injectable Drugs Handbook ('Yellow book') in your ward area. **Assume all unlisted drugs and IV fluids are incompatible – contact Pharmacy for further advice.**

MONITORING (INCLUDING BLOOD TESTS)

- Pre-thrombolysis bloods as outlined in Dosage and Administration.
- APTTs every 6 hours, then re-evaluate in Catheterisation lab at 12 hours after initial procedure.
- Clotting profile including INR every 6 hours.

NURSING PRACTICE POINTS

Required observations are detailed on the Cardiovascular Unit Procedure, Observation & Nursing Record MR/366.1 and Table 2 below.

Once urokinase is ceased maintain sheath patency with intra-arterial infusion of 20 mL/hr sodium chloride 0.9% until sheath removal.

- For requirements post sheath removal, see Vascular Sheath Removal CPP0690
- The patient must be in constant visual range of treating nurse during active treatment.
- The patient must remain nil orally (sips of water are permissible) throughout treatment due to increased bleeding risk and the possible need for surgical intervention in case of complications.
- The patient is nursed in bed as flat as possible and may sit up to no more than a 30-degree angle with close monitoring of the puncture site(s). Ensure two hourly pressure area care is maintained throughout – patients are able to lie on their side as long as leg is straight at site of sheath.
- If accidental dislodgement of the sheath occurs apply manual compression immediately and notify the Interventional Radiologist.
- Avoid intramuscular injections and other invasive procedures during thrombolytic treatment and for 4 hours after cessation. Includes intravenous cannulation unless intravenous access is lost; re-cannulation failures require minimum 10 minutes pressure.
- All injections and infusions are to be labelled as per CPP0222 User Applied Labelling Of Injectable Medicines, Fluids And Lines.

Table 2: Observations Required during Urokinase 12 Hour Infusion				
Observation	**Frequency of observations**			**Management if abnormal result**
	0 to 1 hour	**1 to 2 hours**	**2 hours to end**	
Signs of bleeding Patient to report bleeding/dampness immediately	Continuously and for 3 hours post infusion completion			Stop urokinase, heparin and antiplatelets and seek Medical assistance immediately. See DRG0030 Protamine for heparin reversal if required.
Visual check of insertion site for bleeding/haematoma	15 minutely	30 minutely	Hourly	Report any evidence of haematoma formation to Interventional Radiologist. STOP infusion and mark boundaries with a marker.
Catheter malfunction Leaks at connection site, extravasation, swelling, redness or soreness, pump alarm	30 minutely throughout			Contact Interventional Radiologist immediately.
Pedal pulses and limb observations Colour, warmth, movement, sensation, capillary return	Baseline, then 15 minutely	30 minutely	Hourly	Deterioration in these observations may indicate embolisation or compartment syndrome and require urgent Medical review.
Vital signs Continuous arterial blood pressure via sheath, heart rate, respiratory rate, oxygen saturation	Baseline, then 15 minutely	30 minutely	Hourly	MET call/Code blue as per usual procedure
Neurological observations	Baseline, then 15 minutely	30 minutely	Hourly	Changes in neurological observations can be life-threatening and need immediate medical attention.
Pressure care	2 hourly throughout			See CPP0580 Pressure Injury – Prevention & Management.
Allergic reactions Flushing, urticaria, dyspnoea, hypotension, and anaphylaxis.	Throughout			Contact Medical staff if a reaction occurs – if severe pause the infusion first. Allergic reactions may also occur to the contrast used during angiography.
Infusion reactions Fever, rigors, cyanosis, hypoxemia, acidosis, back pain, and nausea and/or vomiting	Throughout			Most common at the beginning of the infusion. If severe, PAUSE the urokinase infusion, **maintain patency with sodium chloride 0.9% intra-arterial infusion** and contact Medical staff. Symptomatic treatment for mild reactions is usually sufficient.
Urine sample	Each void or 6 hourly for indwelling catheter			Report presence of macroscopic blood (microscopic blood will be present).
Pain	Throughout as needed			Report and document (may indicate bleeding or embolisation). Some patients have extreme pain management issues during initial thrombolysis. Avoid NSAIDs. Consider assessment by Acute Pain Service.

ADVERSE EFFECTS

See also Table 2 above.

Common (>1%)

Bleeding: intracranial, gastrointestinal, genitourinary, retroperitoneal, gingival, epistaxis, microhaematuria, haematoma. Bleeding from puncture site/wound, intramuscular injections. Transient increase in transaminase levels, decrease in haematocrit without clinically detectable bleeding, stroke, thromboembolism, artery dissection, cholesterol embolism, fever, chills.

Infrequent (0.1–1%)

Intrahepatic haemorrhage, renal failure.

Rare (<0.1%)

Hypersensitivity reactions: urticaria, hypotension, dyspnoea, flushing, rash, bronchospasm, anaphylaxis (very rare).

DRUG PRESENTATIONS AND STORAGE

Urokinase 100,000 unit and 500,000 unit vials.
U-Frag, Urokinase Maya Biotech: store in refrigerator at 2 to 8 °C. Protect from light.
Urokinasi EG, Uronase and Syner-KINASE: store below 25 °C. Protect from light.

RELATED DOCUMENTS

SOP0001 Principles of Clinical Care.
CPP0549 High Risk Medications.
DRG0038 Heparin.
DRG0030 Protamine.
CPP0222 User Applied Labelling Of Injectable Medicines, Fluids And Lines.
CPP0287 Medication Administration
CPP0580 Pressure Injury Prevention and Management
CPP0211 Consent For Medical Treatment
CPP0062 Interventional Safety Checklist - Radiology And Cardiovascular Suite
CPP0690 Vascular Sheath Removal
CPP0433 Medical Emergency Responses
POL0209 Recognising And Responding To Clinical Deterioration

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APPENDIX 1 – AVF Thrombosis

AVF THROMBOSIS:

Dosing is varied and determined by the Interventional Radiologist, and administration to the fistula is by the Interventional Radiologist under ultrasound. See Reconstitution above.

- A total of heparin 5,000 units in 5 mL is administered to different parts of the fistula prior to urokinase administration.
- Urokinase 50,000 units/mL reconstituted solution is then administered to different parts of the fistula, generally with a dose of 200,000 units (4 mL) to 500,000 units (10 mL) total dose.
- Dwell time in the fistula is usually 1 hour, and then the urokinase is aspirated from the fistula.
- On occasion extra urokinase may need to be added to the fistula, but still not exceeding a total urokinase dose of 500,000 units.

HDU/ICU bed is required post procedure for adverse reaction monitoring with consideration to increased bleeding risks.
Intravenous access must be in situ and patent.

APPENDIX 2 – CVU Nursing Procedure for Urokinase Intra-arterial Administration

Equipment Required:

- Ensure Special Access Scheme (SAS) form for urokinase is completed
- Urokinase 100,000 units and/or 500,000 units vials obtained from CVU Imprest +/- Pharmacy, including enough to last out of hours (see Table 4 below)
- Infusion order chart (MR/645.0) highlighted for intra-arterial use for urokinase (see **example orders below**)
- Heparin Intravenous Infusion Chart (MR/700.3) for heparin
- NSMC (MR/700.2) for noting heparin and urokinase bolus doses
- Peripheral angiogram pack
- Heparin 25,000 units in 250 mL premixed bag
- Heparin 5000 units/5 mL
- Midazolam 5 mg/5 mL
- Fentanyl 100 microg/2 mL
- 1 litre bag sodium chloride 0.9%
- Sterile spike
- 50 mL luer lock syringe
- Contrast 50 mL
- Chlorhexidine 2% / isopropyl alcohol 70% tinted skin prep 10.5 mL (BD ChloraPrep) or povidone iodine if allergic to chlorhexidine
- Multiple IV 3000s (for securing sheath, catheter and lines)
- 5F sheath
- 5F microcatheter with end-hole and side holes
- Suitable wire
- Micropuncture introducer kit
- 2 x IV access with minimum volume extension tubing for possible sedation
- BD Alaris PCU with 1 x Pump Module 1 x Syringe Module
- Standard giving set (dead space 18 mL)
- Giving set for syringe module with pressure sensing disc (dead space 1.6 to 2.6 mL)
- Appropriate route additive and line labels for all bags and syringes
- Consult with treating Interventional Radiologist for additional requirements

Number of Urokinase Vials Required

Patient weight	**BOLUS** dose of urokinase: 2,000 units/kg	**100,000 unit** vials required	**12-HOUR INFUSION** dose of urokinase: 12 hr x weight (kg) x 2,000 units/kg/hr	**100,000 unit** vials required	**500,000 unit** vials required
40 kg	80,000 units	1	960,000 units	-	2
50 kg	100,000 units	1	1,200,000 units	2	2
60 kg	120,000 units	2	1,440,000 units	-	3
70 kg	140,000 units	2	1,680,000 units	2	3
80 kg	160,000 units	2	1,920,000 units	-	4
90 kg	180,000 units	2	2,160,000 units	2	4
100 kg or more **MAXIMUM**	200,000 units	2	2,400,000 units	-	5

At the time of writing: urokinase 100,000 unit vial costs $151.11 and 500,000 unit vial costs $479.41. The table provides the most cost-effective way of providing the vials (4 x 100,000 unit vials are more expensive than 1 x 500,000 unit vial).

Example orders for 70 kg patient:

Urokinase and heparin bolus doses given in Catheterisation lab must be noted on the NSMC

ONCE ONLY, PRE-MEDICATION & NURSE INITIATED MEDICINES								
Date Prescribed	Medication (Print Generic Name)	Route	Dose	Date/Time of dose	Prescriber/Nurse Initiator (NI) Signature / Print Name	Given by	Date/Time Given	Pharmacy
01/01/23	heparin bolus	intra-arterial	5,000 units	01/01/23 1545	Given in cath lab, see MR 365.83 CVU report [initials]	✓ ✓	01/01/23 1545	
01/01/23	urokinase bolus	intra-arterial	140,000 units	01/01/23 1600	Given in cath lab, see MR 365.83 CVU report [initials]	✓ ✓	01/01/23 1600	

Urokinase 12-hour infusion to be ordered on modified IV Orders MR/645.0

Ballarat Health Services
Putting your health first

Intra-ARTERIAL Intra-ARTERIAL
Commenced: Date ...../...../..... Time .....

ALLERGIES & ADVERSE REACTIONS (ADR)
☑ Nil Known
☐ Unknown (tick appropriate box or complete details below)

DRUG (or other)	Reaction/Type/Date	Initials

Sign A. Doctor Print Doctor Date 01/01/23

UR
Sur
Giv
D.C

PATIENT BRADMA

Attach patient ID Labels to all pages of this form before commencing any documentation.

First Prescriber to Print patient name & check label correct: PATIENT NAME

Intra-ARTERIAL

Medical Order						Nursing Record				
Date	Flask No / Flask Vol mL	Type of Fluid Including Strength	Additive(s) Including Dose	Rate: Hr per flask or mL per hour	Medical Officer's Signature	Start Time / Date	Finish Time / Date	Volume Given: mL	Nurse's Signature	Pharmacist Review
01/01/23	48 mL	sodium chloride 0.9%	Urokinase 1,680,000 units	4 mL/hr	A. Doctor					

Fill out start time and date as per CVU report (Interventional Radiology MR/365.83)

Pre-Procedure:

- Nursing assessment for interventional vascular angiography procedure requiring sedation should be undertaken
- Ensure there are no contraindications to urokinase or heparin administration
- Obtain informed written consent
- Complete correct procedure form
- Patient should be fasted pre-procedure: preferably 6 hours from food, 2 hours from clear fluids
- Ensure Pathology tests as outlined above are available
- IV access x 2 obtained
- Ensure analgesia/sedation available
- Full monitoring, including ECG, $Sp0_2$, blood pressure, respiration rate and temperature is required
- Intranasal oxygen administration only required if clinically indicated

Procedure:

Patient positioned on the CVU table according to required access. The patient is prepped with chlorhexidine (unless known allergy, then povidone iodine is to be substituted) and draped in a sterile fashion. The appropriate Surgical Time Out is to be performed, including patient ID checks and consent. Intra-operative intravenous sedation/pain relief medications given if required and ordered by the interventional radiologist. The interventional radiologist will gain arterial access and an appropriate sheath inserted. The occluded vessel is identified and the catheter through which the urokinase infusion is to be administered, positioned. The catheter and sheath are carefully secured with IV 3000s. Continuous monitoring as described above is to be maintained and monitored for adverse reaction, including vaso-vagal reactions in response to arterial access.