Prescribing Protocol SESLHDPR/713
Caplacizumab for severe Thrombotic thrombocytopenic purpura

Prescribing Protocol Template for New Drugs	
Title	Caplacizumab for severe thrombotic thrombocytopenic purpura (TTP)
Areas where Protocol/Guideline applicable e.g. District, Hospital, ITU, Ward	SESLHD
Areas where Protocol/Guideline not applicable	Nil
Authorised Prescribers	Haematologists
Indication for use	Severe TTP as defined by PLASMIC score
Clinical condition Patient selection: Inclusion criteria (list investigations necessary and relevant results)	The PLASMIC score is used in hospitalised patients with suspected TTP in whom ADAMTS results are not yet available and where early intervention may be of benefit. A point is scored for each of the following: • a platelet count below 30, • the presence of haemolysis, • the absence of active cancer, • the absence of solid organ or stem cell transplant, • the presence of an MCV <90fL
Contra-indications	Hypersensitivity to caplacizumab or any of the excipients.

Precautions	• Active clinically significant bleeding, see *Management of complications*, below.
	• Increased risk of bleeding, seek haematology advice;
	  ○ Concomitant use of oral anticoagulants, anti-platelets, LMWH and/or high dose heparin
	  ○ In patients with coagulopathies
	  ○ In patients undergoing surgery

Place in Therapy State whether drug to be used as first, second or third line. When not first line, describe therapies to be used first. (Consider using algorithm)	Caplacizumab is used in patients suspected of having TTP who have a high PLASMIC score
If part of combination therapy, list other drugs	Use in combination with plasma exchange

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Dosage (Include dosage adjustment for specific patient groups)	Day 1: 10mg IV infusion Day 2: 10mg subcut injection Day 3: 10mg subcut injection
Duration of therapy	3 days
Important Drug Interactions	Use with caution in patients on anticoagulation or antiplatelet agents
Administration instructions	Reconstitute the vial using the prefilled syringe and vial adaptor provided. Add the solvent slowly and mix gently to avoid foaming. With the syringe still attached, allow the vial to stand for 5 minutes at room temperature before drawing the dose back into the syringe. **The first dose must be given by IV injection.** First dose: caplacizumab 10mg via IV injection given as a bolus at least 15 minutes prior to plasma exchange. Subsequent doses: caplacizumab 10mg via subcut injection into the abdomen after completion of each plasma exchange.
Monitoring requirements	**Caplacizumab increases risk of bleeding.** Monitor for signs of severe bleeding, including epistaxis, gingival bleeding, upper GI haemorrhage and menorrhagia.
Management of complications	**Close coordination with haematologist.** In the case of active, clinically significant bleeding, treatment with caplacizumab should be interrupted. If needed, the use of vWF-containing concentrate can be considered. Re-starting treatment can be considered on the advice of the treating haematologist.
Basis of Protocol/Guideline (including sources of evidence, references)	Scully M et al. Caplacizumab Treatment for Acquired Thrombotic Thrombocytopenic Purpura. N Engl J Med 2019; 380:335-346 Society of Hospital Pharmacists of Australia (2021) *Australian Injectable Drugs Handbook 8th Ed*. Online available MIMS Online (2021) MIMS Australia Online available
Groups consulted in development of this protocol	Cancer Services Clinical Stream Quality Use of Medicines Pharmacy

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GOVERNANCE	
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Chairperson, QUM Committee	Dr John Shephard
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