

**Prescribing Protocol SESLHDPR/655  
Ceftolozane/tazobactam**

<b>Title</b>	Ceftolozane/tazobactam Prescribing Protocol
<b>Areas where Protocol/ Guideline applicable</b>	SESLHD Inpatient ward areas including intensive care
<b>Areas where Protocol/ Guideline not applicable</b>	Outpatient, Paediatrics
<b>Authorised Prescribers</b>	Infectious Diseases physician or Microbiologist
<b>Indication for use</b>	<p>Indicated for the treatment of the following infections in adults suspected or proven to be caused by designated susceptible pathogen which are resistant to all other available agents like penicillin and enzyme inhibitor combination (piperacillin/tazobactam), carbapenem (meropenem) and fluoroquinolone (ciprofloxacin):</p> <ul style="list-style-type: none"> <li>- Complicated intra-abdominal infections in combination with metronidazole</li> <li>- Complicated urinary tract infections, including pyelonephritis</li> <li>- Hospital acquired Pneumonia including Ventilator-associated pneumonia</li> </ul> <p>Infection caused by isolates producing ESBL and OXA-48 carbapenemase but NOT AmpC, KPC and MBL producing organisms.</p>
<b>Clinical condition</b>	Indicated for the treatment of infections in adults suspected or proven to be caused by designated susceptible microorganisms which are resistant to all other available agents like penicillin and enzyme inhibitor combination (piperacillin/tazobactam), carbapenem (meropenem) and fluoroquinolone (ciprofloxacin)
<b>Contra-indications</b>	Known hypersensitivity to ceftolozane/tazobactam, or members of the cephalosporin class, or other members of the beta-lactam class.
<b>Precautions</b>	<p>Ceftolozane/tazobactam is eliminated by the kidneys.</p> <p>Dosage adjustment is required with creatinine clearance &lt;50mL/min</p> <p>Sodium restriction – each vial contains 230mg (10mmol) sodium</p>
<b>Place in Therapy</b>	<p>Directed therapy based on positive microbiology.</p> <p>Second or third line depending on clinical picture, MIC, patient tolerability and resistance mechanism.</p> <p>GuidanceMS “Red” antibiotic requiring prior ID/Micro approval for initiation; only to be stocked in Pharmacy.</p> <p>It will be used for multi-drug resistant Pseudomonas and other organism such as isolates producing ESBL and OXA-48 carbapenemase which are susceptible to ceftolozane-tazobactam</p>

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<b>Dosage</b> (Include dosage adjustment for specific patient groups)	Dose by type of infection in patients with a CrCl > 50 mL/min		
	<b>Infection Type</b>	<b>Dose</b>	<b>Frequency</b>
	Complicated intra-abdominal infection*	1000mg/500mg	Every 8 hours
	Complicated urinary tract infections, including pyelonephritis	1000mg/500mg	Every 8 hours
	Hospital acquired Pneumonia including Ventilator-associated Pneumonia	2000mg/1000mg	Every 8 hours
*Used in conjunction with metronidazole 500mg IV every 8 hours			
Ceftolozane/tazobactam is eliminated primarily by the kidneys - Dosage adjustments CrCl < 50mL/min required			
<b>Duration of therapy</b>	Complicated intra-abdominal infection: up to 14 days or as approved by Infectious Disease Complicated urinary tract infections, including pyelonephritis: 7 days or as approved by Infectious Disease		
<b>Important Drug Interactions</b>	Nil		
<b>Administration instructions</b>	Infuse intravenously over 60 minutes Reconstitute with either water for injection or 0.9% sodium chloride, add to 100mL of compatible fluid <u>Storage:</u> 2°C - 8°C. Refrigerate. Do not freeze.		
<b>Monitoring requirements</b>	Resolution of clinical signs and symptoms; improvement in laboratory parameters; clearance of blood cultures; serum creatinine levels.		
<b>Management of complications</b>	Consideration of discontinuation of therapy and management of the specific complication, if severe		
<b>Basis of Protocol/Guideline</b> (including sources of evidence, references)	Product Information TGA available online for ceftolozane-tazobactam (Zerbaxa) attached accessed 13/8/2021 Cluck D et al, Ceftolozane-tazobactam: A new generation cephalosporin, AJHSP 2015 Product information (MIMS online) for meropenem 08/03/2016. Accessed 13/08/2018 Product information (MIMS online) for ciprofloxacin 28/02/2012. Accessed 13/08/2018 Australian Medicines Handbook (online), Ceftolozane/tazobactam monograph. Accessed 14/08/2019 Australian Injectable Drugs Handbook, 7 <sup>th</sup> Edition (online), Ceftolozane/tazobactam monograph. Accessed 14/08/2019		
<b>Groups consulted in development of this protocol</b>	DIDISH, AMS CAAG (SESLHD/ISLHD)		

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<b>GOVERNANCE</b>	
Enactment date	September 2019
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Chairperson, QUM Committee	Dr John Shephard
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