

Target Product Profile – Gram-negative – Therapeutic Product

Variable	Minimal Requirement	Ideal Requirement
Product Indication	Oral step down for hospitalized community-acquired bacterial pneumonia (hCABP), hospital-acquired bacterial pneumonia HABP or ventilator-associated pneumonia (VAP)	Oral step down for hospitalized community-acquired bacterial pneumonia (hCABP), hospital-acquired bacterial pneumonia HABP or ventilator-associated pneumonia (VAP)
Organisms Covered	Broad or narrow spectrum of coverage, targeting antibiotic-susceptible and -resistant Enterobacterales, including MDR, CRE, ESBL-producing pathogens	Broad or narrow spectrum of coverage, targeting antibiotic-susceptible and -resistant Enterobacterales, including MDR, CRE, ESBL-producing pathogens, <i>Pseudomonas aeruginosa</i> and/or <i>Acinetobacter baumannii</i>
Patient Population	Adults discharged from a healthcare setting for the treatment of a confirmed serious Gram-negative infection	Adults and children (>1yr) discharged from a healthcare setting for the treatment of a confirmed serious Gram-negative infection
Treatment Duration	10 – 14 days	5 – 10 days
Delivery Mode	Oral	Oral or oral and IV
Dosage Form	Tablet, capsule, or other acceptable oral dosage form	Tablet, capsule
Regimen	Up to 3 doses/day	once daily
Efficacy	Equal to the standard of care for all targeted indications	Greater than or equal to the standard of care for all targeted indications
Risk/Side Effects	Manageable drug interactions; clean safety profile; safety margin 5-10X over effective dose	Manageable drug interactions; clean safety profile; safety margin >10X over effective dose (higher for community indications)
Stability	At least 3 month solid state stability at 4C	At least 3 month solid state stability at 4C and 25C
Cost	Equivalent to current treatment regimens in HIC	COGs that are compatible with launch in LMICs
Specific Population Claims		
Overall Value Proposition: Convenient oral step down antibiotic active against antibiotic-resistant Gram-negative pathogens enabling timely transition from hospital to outpatient setting		