I.5	Antibiotics for necrotizing fasciitis
Does the application adequately address the issue of the public health need for the medicine?	☒ Yes ☐ No ☐ Not applicable Comments:
Briefly summarize the role of the proposed medicine(s) relative to other therapeutic agents currently included in the Model List, or available in the market.	Necrotizing fasciitis (the most severe among the spectrum of skin and soft tissue infections) requires further evaluation for consistency since for other types of infections the EML/EMLc specifically also considers severe infections. x Piperacillin-tazobactam in combination with clindamycin (for empiric treatment) x Ceftriaxone in combination with metronidazole (this combination should be used only after Streptococcus pyogenes necrotizing fasciitis has been ruled out) x Vancomycin (in combination with one of the above-mentioned options if methicillin-resistant Staphylococcus aureus is suspected)
Have all important studies and all relevant evidence been included in the application?	☒ Yes ☐ No ☐ Not applicable If no, please provide brief comments on any relevant studies or evidence that have not been included:
Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed indication?	☒ Yes ☐ No ☐ Not applicable Briefly summarize the reported benefits (e.g. hard clinical versus surrogate outcomes) and comment, where possible on the actual magnitude and clinical relevance of benefit associated with use of the medicine(s). Is there evidence of efficacy in diverse settings (e.g. low-resource settings) and/or populations (e.g. children, the elderly, pregnant patients)?
Does the application provide adequate evidence of the safety and adverse effects associated with the medicine?	☒ Yes ☐ No ☐ Not applicable Comments: These antibiotics are widely used and included in EML

Are there any adverse effects of concern, or that may require special monitoring?	☐ Yes ☒ No ☐ Not applicable Comments:
Briefly summarize your assessment of the overall benefit to risk ratio of the medicine (e.g. favourable, uncertain, etc.)	Favourable
Briefly summarize your assessment of the overall quality of the evidence for the medicine(s) (e.g. high, moderate, low etc.)	low
Are there any special requirements for the safe, effective and appropriate use of the medicine(s)**?** (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)	☐ Yes ☒ No ☐ Not applicable Comments:
Are you aware of any issues regarding the registration of the medicine by national regulatory authorities? (e.g. accelerated approval, lack of regulatory approval, off-label indication)	☐ Yes ☐ No ☒ Not applicable Comments:
Is the proposed medicine recommended for use in a current WHO Guideline approved by the Guidelines Review Committee? (refer to: https://www.who.int/publications/who-guidelines)	☐ Yes ☒ No ☐ Not applicable Comments:
Briefly summarize your assessment of any issues regarding access, cost and affordability of the medicine in different settings.	These antibiotic are already included in EML
Any additional comments	

Based on your assessment of the application, and any additional evidence / relevant information identified during the review process, briefly summarize your proposed recommendation to the Expert Committee, including the supporting rationale for your conclusions, and any doubts/concerns in relation to the listing proposal.	Agree with inclusion of the following antibiotics for treatment of necrotizing fasciitis in EML/EMLc Adults: Piperacillin–tazobactam (IV): 4 g + 500 mg every 6 hours AND Clindamycin (IV): 900 mg every 8 hours. If Streptococcus pyogenes has been ruled out Ceftriaxone (IV): 2 g once a day AND Metronidazole (IV): 500 mg every 8 hours can also be used. if MRSA is suspected Vancomycin (IV) 15-20 mg/kg every 12 hours should be added to both of the above-mentioned options. Children: Piperacillin–tazobactam (IV): 100 mg/kg per dose of piperacillin component, given every 8 hours AND clindamycin (IV): x Neonates: 5 mg/kg per dose, given every 8 hours x Children: 10 mg/kg per dose, given every 8 hours If Streptococcus pyogenes has been ruled out Ceftriaxone (IV): 80 mg/kg per dose, once a day AND metronidazole (IV) can also be used: x Neonates: 7.5 mg/kg per dose, given every 12 hours x Children: 7.5 mg/kg per dose, given every 8 hours if MRSA is suspected Vancomycin (IV) should be added to both of the above-mentioned options as follows: x Neonates: 15 mg/kg per dose, given every 12 hours x Children: 15 mg/kg per dose, given every 8 hours Agree with inclusion of additional strength IV formulations of ceftriaxone (2 g powder for injection), clindamycin (600 mg and 900 mg) and vancomycin (500 mg and 1 g) be added to the EML to better meet the dosing needs of adults for this indication
References (if required)	