CLINICAL EFFECTIVENESS OF CEFTAROLINE FOSAMIL IN THE TREATMENT OF COMMUNITY-ACQUIRED PNEUMONIA IN ADOLESCENTS AND CHILDREN: A SYSTEMATIC REVIEW AND META-ANALYSIS

Health Technology Assessment Philippines

PICO Table

Population	Hospitalized patients of different ages (i.e., adults, adolescents, and children over the age of two months) with moderate to severe community-acquired pneumonia (CAP)
Intervention	Ceftaroline fosamil 600 mg powder for concentrate for solution for injection *Nominator: Pfizer*
Comparator	Ceftriaxone (2g q24hr)* OR Cefotaxime (1–2 g IV q8hr)* OR Ampicillin/sulbactam (1.5g q6hr)* OR PLUS Macrolide (e.g., Azithromycin* OR Clarithromycin* OR Erythromycin**) *For moderate-risk and high-risk CAP **For high-risk CAP only OR Ceftriaxone monotherapy OR Ceftriaxone with Vancomycin *(note: vancomycin is also in the PNF)*

PICO Table

Population	Hospitalized patients of different ages (i.e., adults, **adolescents, and children over the age of two months**) with moderate to severe community-acquired pneumonia (CAP) *Note: Recommendation for adult to be released separately*
Intervention	Ceftaroline fosamil 600 mg powder for concentrate for solution for injection *Nominator: Pfizer*
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PICO Table

Outcome	**Effectiveness**	**Safety**
	1. Clinical cure rates 2. All-cause mortality (cumulative incidence/ proportion) 3. Mortality rate as treatment failure 4. Length of hospital stay (in days) 5. Length of time to achieve clinical response	1. Adverse events 2. Serious adverse events 3. Discontinuation because of adverse events 4. Death

Red: Outcomes from the HTAC-approved PICO not reported by the studies

Policy Question

*Among **hospitalized adolescents and children** **over the age of two months**, should **ceftaroline fosamil** for the treatment of moderate to severe community-acquired pneumonia compared to non-pseudomonal beta-lactams with or without macrolides be recommended for government financing?*

Research Questions

C1: Responsiveness to Magnitude and Severity

RQ1. As a public health problem, what is the magnitude and severity of community-acquired pneumonia (CAP) among hospitalized adolescents and children over the age of two months?

C2: Clinical efficacy, effectiveness and safety

RQ2.1. Among hospitalized adolescents and children over the age of two months, with moderate to severe CAP, what is the efficacy and/or effectiveness (i.e., clinical cure rates; all-cause mortality; mortality rate as treatment failure; and length of hospital stay) of ceftaroline fosamil versus non-pseudomonal beta-lactams (i.e., ceftriaxone, cefotaxime, ampicillin/sulbactam) with or without macrolides (i.e., azithromycin, clarithromycin, erythromycin)?

RQ2.2. Among hospitalized adolescents and children over the age of two months, with moderate to severe CAP, what is the safety (i.e., adverse events, serious adverse events, discontinuation because of adverse events, and death) of ceftaroline fosamil versus non-pseudomonal beta-lactams (i.e., ceftriaxone, cefotaxime, ampicillin/sulbactam) with or without macrolides (i.e., azithromycin, clarithromycin, erythromycin)?

RQ 2.3. What are the recommendations and guidelines of HTA agencies and ministries of health on the use of ceftaroline fosamil in hospitalized adolescents and children over the age of two months ?

BACKGROUND

Etiology (Potential Pathogens) (National Antibiotic Guidelines, 2017)

CAP in Infants and Children ≤ 5 years old	CAP in children > 5 y.o. and adolescents
• *S. pneumoniae* (30-50%) • *H. influenzae* type b (10-30%) • *S. aureus* • *K. pneumoniae* • Non-typeable *H. influenzae*	• *S. pneumoniae* • *M. pneumoniae* • *C. pneumoniae*

Spectrum of Activity of Antibiotics

Pathogen	NON-PSEUDOMONAL BETA-LACTAMS					MACROLIDES		
	Ceftaroline	Ceftriaxone	Cefotaxime	Ampicillin/ Sulbactam	Azithromycin	Clarithromycin	Erythromycin	Vancomycin
S. pneumoniae								
A. baumannii								
H. influenzae								
MRSA								
P. aeruginosa								
S. aureus								
H. parainfluenzae								
K. pneumoniae								
E. coli								

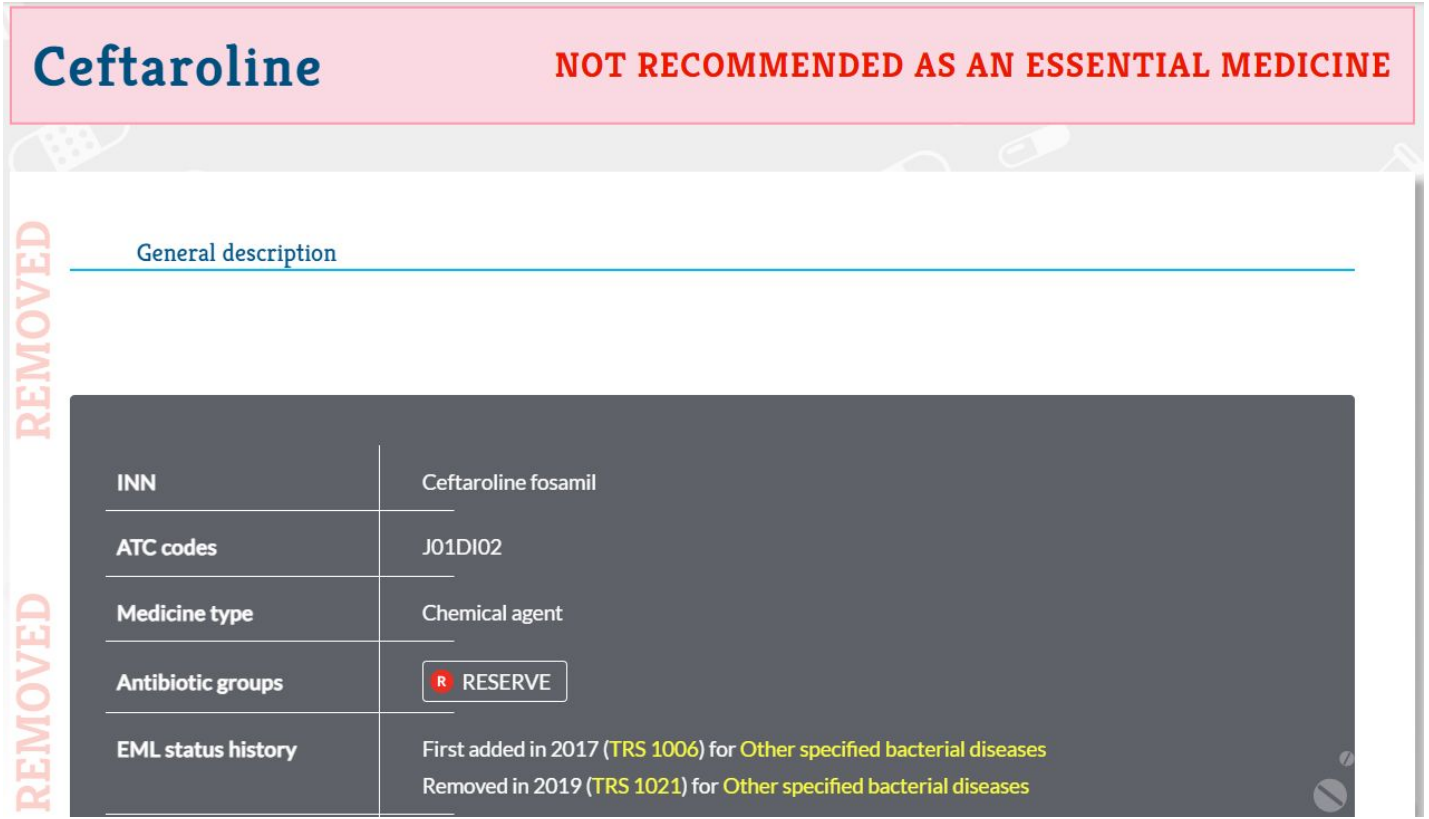
Key Risk Factors for MRSA Infections in Children

- Skin trauma (e.g., turf burns, lacerations, abrasions, cosmetic body shaving, body piercing, tattoo placement) (Miller et al., 2007)
- Frequent skin-to-skin contact (CDC, 2003)
- Sharing contaminated personal items or equipment (CDC, 2003)

  Examples: Razors, sports equipment, towels (not cleaned/laundered between users)
- Crowding (CDC, 2006; Begier et al., 2004)
- Challenges in maintaining personal cleanliness and hygiene (Begier et al., 2004)
- Limited access to health care (Young et al., 2004)
- Frequent exposure to antimicrobial agents (Baggett et al., 2004; Guillemot et al., 2004)

WHO EML Listing [1 of 2]

- Not recommended in the WHO EML
- A **Reserve group** antibiotic that did not meet the revised criteria for inclusion in the WHO EML



WHO EML Listing [2 of 2]

Summary of evidence and Expert Committee recommendations

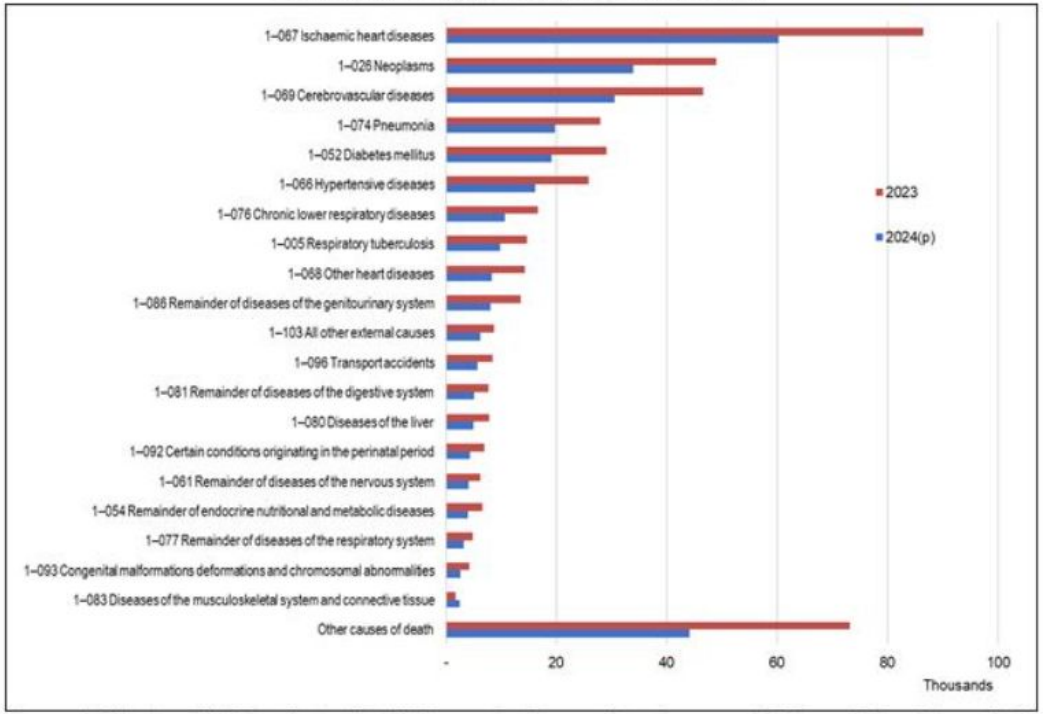
With regard to the EML listing of antibiotics, the Committee endorsed revised criteria for the inclusion of Reserve group antibiotics on the Model List. Namely, Reserve group antibiotics should be included individually on the Model List when they have a favourable benefit-risk profile and proven activity against "Critical Priority" or "High Priority" pathogens as identified by the WHO Priority Pathogens List, most notably carbapenem resistant Enterobacteriaceae. Subsequently, the Committee recommended the removal of aztreonam, fourth- and fifth-generation cephalosporins (as classes), tigecycline and daptomycin from the EML and EMLc as these antibiotics did not meet the revised criteria for inclusion on the Model Lists as individual Reserve group agents.

CI: RESPONSIVENESS TO DISEASE MAGNITUDE AND SEVERITY

Burden of Disease

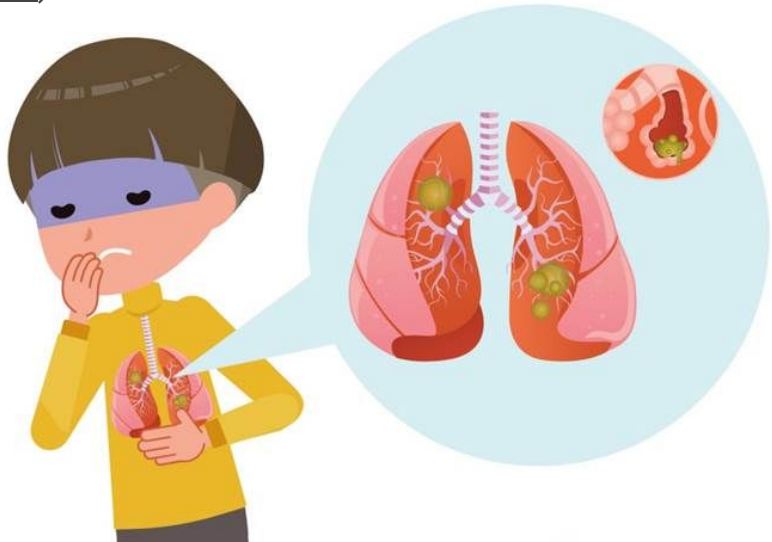
- Locally, pneumonia emerged as the fourth leading cause of death with 19,842 cases (PSA, 2024)
- Globally, CAP is the **eighth leading cause of mortality and the first among infectious causes of mortality**. The mortality rate of intensive care unit (ICU) patients with severe pneumonia is at 23% (Regunath & Oba, 2024).

Figure 1. Top 20 Causes of Mortality, Philippines: January to August, 2023 and 2024



Burden of Disease in the Pediatric Population

- The incidence of CAP in developing countries is 0.29 per child-year (Cardinale et al., 2013).
- A study from 2016 noted that the incidence per 100,000 children aged less than 5 years old in the Philippines is about 10,500.
- In terms of mortality, pneumonia in general, is the leading cause of mortality in 2022 occurring at 9.9 per 100,000 children (Department of Health, 2022).
- Specifically, it is the 3rd leading cause of mortality in children ages 5 to 9 years old. It is also the 2nd leading cause of mortality in and 10 to 14 years old, respectively



Potential Pathogens for CAP included in the ARSP 2023

- Resistance data for **117,398 bacterial isolates*** coming from 24 hospital based bacteriology laboratories and 1 gonococcal surveillance site were analyzed for 2023.
- 46%-62% of specimens came from adults 20-64 yo; **2%-10% from 19 years old and below**

Pathogen	Percentage (Number) of bacterial isolates
Streptococcus pneumoniae	**0.40%** (427/117,398)
Acinetobacter baumannii	**5.79%** (6,800/117,398)
Haemophilus influenzae	**0.33%** (390/117,398)
Pseudomonas aeruginosa	**8.25%** (9,680/117,398)
Staphylococcus aureus	**6.67%** (7,834/117,398)
MRSA	**2.09%** (2,448/117,398)
Klebsiella pneumoniae	**13.77%** (16,164/117,398)
Escherichia coli	**11.50%** (13,496/117,398)

Key findings:
Data from ARSP (2023) shows that the most detected pathogen is *K. pneumoniae.*

**Note: Data not specific to CAP*

Summary of Resistance Data (ARSP 2023)

Data not specific to CAP

Resistance rates of pathogens for all specimens

Pathogen	No. of Isolates Tested	Ceftaroline	Ceftriaxone	Cefotaxime	Ampicillin/Sulbactam	Azithromycin	Erythromycin	Vancomycin	MDR (%)	Possible XDR (%)
S. pneumoniae	427	**Not included in the drugs routinely tested for the following reasons:** (1) not recommended for routine testing by CLSI (2) antibiotic discs and E-tests are not available locally.	(NM): 0.84% (M): 1.67%				7.62%	0.00		
H. influenzae	390		0.59%	0.00%	10.96%	0.00%				
P. aeruginosa	9,680								28.3%	18.2%
A. baumannii	6,800		26.17%	45.63%	49.00%				58.1%	49.0%
MRSA	2,448						18.09%	4.34%		
S. aureus	7,834						11.94%	2.01%		
K. pneumoniae	16,164		43.92%						57.7%	26.1%
E. coli	13,496		37.13%						59.4%	14.2%

Percentage of Resistant Isolates	≤ 5%	> 5 - 10%	> 10 - 30%	> 30%

Recommendations on Ceftaroline testing based on CLSI

Bacteria	Recommendation on Ceftaroline testing based on CLSI M100 33rd ed (2023)
S. aureus	**Tier 3:** Antimicrobial agents that are appropriate for routine, primary testing **for institutions that serve patients at high risk for multi-drug resistant organisms (MDROs)** but should only be reported following cascade reporting rules established at each institutions
MRSA	
S. pneumoniae	**Tier 4**: Antimicrobial agents that may warrant testing and reporting by clinician request **if antimicrobial agents in other tiers are not optimal because of various factors**
H. influenzae	
K. pneumoniae	
E. coli	
A. baumannii	Not recommended for testing
P. aeruginosa	

Note: Same recommendations from CLSI M100 34th ed (2024) and CLSI M100 35th ed (2025).

European Committee on Antimicrobial Susceptibility Testing (2025)

Pathogen	NON-PSEUDOMONAL BETA-LACTAMS		MACROLIDES
	Ceftaroline	Ampicillin/ Sulbactam	Vancomycin
Staphylococcus spp. (such as S. aureus)	*S. aureus* is considered resistant to ceftaroline when drug concentration reaches > 2 mg/L	Most *S. aureus* are penicillinase producers and some are methicillin resistant.	Resistant isolates are rare or not yet reported
S. pneumoniae	*No established breakpoint*	The addition of a beta-lactamase inhibitor does not add clinical benefit.	
H. influenzae	*No established breakpoint*	*No established breakpoint*	Macrolides in general: Clinical evidence for the efficacy of macrolides in respiratory infections is conflicting due to high spontaneous cure rates.

% Susceptibility in Asia-Pacific Region (Sader et al., 2018)

- 4,321 bacterial isolates from patients with community-acquired bacterial pneumonia in Europe, Asia-Pacific, and Latin America were collected from 2015-2017
  Note: No age specified

Pathogen	Ceftaroline	Ceftriaxone	Ampicillin	Azithromycin	Erythromycin	Vancomycin
S. pneumoniae	99.7%	85.3%		49.6%		
H. influenzae	99.2%	100.0%		98.4%		
H. parainfluenzae		100.0%	100.0%	100.0%		
S. aureus	94%	68.1%			74.1%	100%
MRSA	81.1%				45.9%	100%

Responsiveness to Magnitude and Severity [1 of 2]

RQ.1. As a public health problem, what is the magnitude and severity of moderate to severe community-acquired pneumonia (CAP) among adolescents, and children over the age of two months?

[Judgment]

Pneumonia is one of the leading causes of death in the Philippines accounting for **4.9% of all deaths in 2022.** Recent data from 2024 shows an increase, with pneumonia becoming the **fourth leading cause of death**, resulting in **6.5% of all deaths** (Philippine Statistics Authority, 2024). Globally, the mortality rate of intensive care unit (ICU) patients with severe pneumonia is reported at 23% (Regunath & Oba, 2024).

Among children, local data shows that pneumonia remains a significant health concern. It is the leading cause of mortality with a rate of 9.9 deaths per 100,000 children (Department of Health, 2022). Specifically, it is the third leading cause of death for children aged 5 to 9 years old and the second leading cause among those aged 10 to 14 years old.

Focusing specifically on community-acquired pneumonia (CAP), it ranks as the **eighth leading cause of overall mortality** and is the **first among the infectious causes of mortality**. In developing countries, the incidence of CAP is 0.29 per child-year (Cardinale et al., 2013). In a study from 2016, the incidence in Filipino children less than 5 years old is about 10,500 per 100,000.

Responsiveness to Magnitude and Severity [2 of 2]

RQ.1. As a public health problem, what is the magnitude and severity of moderate to severe community-acquired pneumonia (CAP) among adolescents, and children over the age of two months?

The following are the potential pathogens that cause CAP among children and adolescents according to the NAG (2017): *S. pneumoniae*, *H. influenzae* type b, *S. aureus, K. pneumoniae,* non-typeable *H. influenzae, M. pneumoniae, and C. pneumoniae.* Among these, *S. pneumoniae* (30-50%) and *H. influenzae type b* (10-30%) are the most common cause of CAP in children. The ARSP 2023* shows that the resistance rates of ***S. pneumoniae*** against ceftriaxone using non-meningitis and meningitis breakpoints are 0.84% and 1.67%, respectively. The lowest and highest resistance rates for ***S. pneumoniae*** were 0% for vancomycin and 7.62% for erythromycin. Resistance rates of ***H. influenzae*** was highest for ampicillin/sulbactam at 10.96% and lowest for azithromycin and cefotaxime at 0%, with 0.59% resistance for ceftriaxone.

The resistance rates of less common pathogens causing CAP in children and adolescents are the following:

- *S. aureus:* Erythromycin (11.94%), Vancomycin (2.01%)
- *K. pneumoniae:* Ceftriaxone (43.92%)

Meanwhile, resistance for *M. pneumoniae* and *C. pneumoniae* is not reported by ARSP.

There is **no local data for the resistance of CAP-causing pathogens to ceftaroline fosamil** as this is currently not being tested by RITM. Note that most isolates (n=117,398) from the ARSP (2023) came from patients aged 20 to 64 years old (~40%-60%) while ~2% to 10% came from patients aged 19 years old and below while the rest came from patients aged 65 years old and above.

No local data was found reporting the case fatality rates (CFR) of CAP among the pediatric population disaggregated by bacterial pathogen. A local 2018 study reported the following CFRs of CAP among hospitalized adults (i.e. ≥ 14 years old and older) disaggregated by bacterial pathogen: *K. pneumoniae* (2.06%), *H. influenzae* (1.12%), *S. pneumoniae* (0.93%), *and S. aureus* (0.75%).

**ARSP 2023 data is not specific to CAP*

C2.I: EFFICACY, EFFECTIVENESS AND SAFETY

Summary of Included Studies

Studies	Blumer et al. (2017)	Cannavino et al. (2016)
Setting	USA, Georgia, Ukraine	Poland, Spain, USA, Bulgaria, Georgia, Greece, Hungary, Ukraine
Population	Pediatric patients 2 months to <18 yo, hospitalized with complicated community-acquired bacterial pneumonia (CABP) N = 38 patients	Pediatric patients 2 months to <18 yo, hospitalized with CABP N = 160 patients
Intervention	Ceftaroline fosamil IV (n = 29 patients)	Ceftaroline fosamil IV (n = 121 patients)
Comparator	Ceftriaxone IV PLUS Vancomycin IV (n = 9 patients)	Ceftriaxone IV (n = 39 patients)
Outcome	Clinical response Clinical stability Clinical cure at TOC and EOT Clinical failure AEs SAEs Death, discontinuation due to AEs	Clinical cure/failure at TOC and EOT TEAEs (includes serious adverse events, deaths and discontinuation due to AEs)
Causative agents	*S. pneumoniae, M. catarrhalis, S. pyogenes, MSSA, and E. coli*	Gram-positive cocci in clusters on sputum Gram stain, *P. aeruginosa*, or atypical pathogens (i.e. *C. pneumoniae, M. pneumoniae and Legionella spp.)*

Summary of efficacy outcomes

Outcomes	Pooled data for pediatric patients (2 months to <18 yo)
	Interpretation (Values)
Clinical cure rates (EOT)	**Inconclusive** (RR 0.96; 0.82 to 1.13)
Clinical cure rates (TOC)	**Inconclusive** (RR 0.93; 0.81 to 1.06)
All-cause mortality	**Inconclusive** (RR 0.97; 0.10 to 9.03)
Length of Hospital Stay	*None reported*

Summary of safety outcomes

Outcomes	Pooled data for pediatric patients (2 months to <18 yo)
	Interpretation (Values)
Treatment-Emergent Adverse Events (TEAEs)	**Inconclusive** (RR 0.84; 0.61 to 1.15)
Serious adverse events	**Inconclusive** (RR 0.86; 0.20 to 3.68)
Discontinuation because of adverse event	**Inconclusive** (RR 1.71; 0.21 to 14.09)

C2. Efficacy, Effectiveness, and Safety

RQ.2.1. Among hospitalized adolescents and children over the age of two months with moderate to severe CAP, what is the efficacy and/or effectiveness (i.e., clinical cure rates; all-cause mortality; mortality rate as treatment failure; and length of hospital stay) of ceftaroline fosamil versus non-pseudomonal beta-lactams (i.e., ceftriaxone, cefotaxime, ampicillin/sulbactam) with or without macrolides (i.e., azithromycin, clarithromycin, erythromycin) or vancomycin?

[Judgment]

The systematic review included two randomized controlled trials (RCTs) that enrolled pediatric patients. Both studies evaluated for clinical cure rates at end of treatment and test-of-cure, one study for all-cause mortality, while none investigated mortality rate as treatment failure and length of hospital stay.

Clinical Cure Rates: Clinical cure rates were evaluated at end of treatment (EOT) and test-of-cure (TOC).

- **Clinical cure rates at EOT:** Based on two (2) studies with moderate certainty of evidence, there is **inconclusive evidence** between ceftaroline fosamil and ceftriaxone with or without vancomycin (RR 0.96; 95% CI 0.82 to 1.13; *moderate certainty of evidence*).
- **Clinical cure rates at TOC:** Based on two (2) studies with moderate certainty of evidence, there is **inconclusive evidence** between ceftaroline fosamil and ceftriaxone with or without vancomycin (RR 0.93; 95% CI 0.81 to 1.06; *moderate certainty of evidence*).

All-Cause Mortality: Based on 1 RCT with very low certainty of evidence, there is **inconclusive** evidence between ceftaroline fosamil and ceftriaxone (RR 0.97; 95% CI 0.10 to 9.03; *very low certainty of evidence*).

Mortality Rate as Treatment Failure: None of the studies investigated this outcome.

Length of Hospital Stay: None of the studies investigated this outcome.

C2. Efficacy, Effectiveness, and Safety

RQ.2.2. Among hospitalized adolescents and children over the age of two months with moderate to severe CAP, what is the safety (i.e., adverse events, serious adverse events, discontinuation because of adverse events, and death) of ceftaroline fosamil versus non-pseudomonal beta-lactams (i.e., ceftriaxone, cefotaxime, ampicillin/sulbactam) with or without macrolides (i.e., azithromycin, clarithromycin, erythromycin) or vancomycin?

[Judgment]

The systematic review included two randomized controlled trials (RCTs) that enrolled pediatric patients. Both studies evaluated for treatment-emergent adverse events, serious adverse events, and discontinuation of drug from adverse events.

Treatment-emergent AEs (TEAEs): Based on two (2) RCTs with very low certainty of evidence, there was **inconclusive evidence** (RR 0.84; 95% CI 0.61 to 1.15; *very low certainty of evidence*) between ceftaroline fosamil compared to ceftriaxone with or without vancomycin. The most common TEAEs reported were diarrhea, headache, insomnia, and hypokalemia.

Serious Adverse Events (SAEs): Based on two (2) RCTs with low certainty of evidence, there was **inconclusive evidence** (RR 0.86; 95% CI 0.20 to 3.68; *low certainty of evidence*) between ceftaroline fosamil compared to ceftriaxone with or without vancomycin. The most common SAEs among children are upper and lower respiratory tract infection*.

*In life-threatening infections, timely and effective antimicrobial therapy is critical, and the failure of an antibiotic to achieve its intended therapeutic effect represents a significant hazard to the patient population. The ICH guidelines emphasize this perspective by stating that "***a significant hazard to the patient population, such as lack of efficacy with a medicinal product used in treating life-threatening disease constitutes a safety concern***".

C2. Efficacy, Effectiveness, and Safety

RQ.2.2. Among hospitalized adolescents and children over the age of two months with moderate to severe CAP, what is the safety (i.e., adverse events, serious adverse events, discontinuation because of adverse events, and death) of ceftaroline fosamil versus non-pseudomonal beta-lactams (i.e., ceftriaxone, cefotaxime, ampicillin/sulbactam) with or without macrolides (i.e., azithromycin, clarithromycin, erythromycin) or vancomycin?

[cont.]

Discontinuation of drug from AEs: Based on two (2) RCTs with moderate certainty of evidence, there was **inconclusive evidence** (RR 1.71; 95% CI 0.21 to 14.09; *moderate certainty of evidence*) between ceftaroline fosamil compared to ceftriaxone with or without vancomycin. The most common AE leading to discontinuation of ceftaroline fosamil among children are increase in liver enzymes, development of rash and pruritus, and headache.

Given that the current evidence remains inconclusiveness, further studies in the pediatric population are necessary.

C2.2: REVIEW OF GUIDELINES

SUMMARY OF GUIDELINE RECOMMENDATIONS

3 Guidelines for the Pediatric Population	
3 NOT INCLUDED in the Guidelines	
2021 CPG in the Evaluation and Management of Pediatric CAP (PAPP/PIDSP, 2021)	Does not include the use of ceftaroline fosamil for CAP among infants and children aged 3 months to 18 years
National Antibiotics Guidelines (DOH, 2017)	Does not include the use of ceftaroline fosamil for moderate- and high-risk CAP among infants and children up to 5 years old
OHG for Children (2023) OHG for Adolescents (2023)	Does not include the use of ceftaroline fosamil for non-severe and severe CAP among children under 10 years old and adolescents

C2. Review of Guidelines

RQ2.3: What are the recommendations and guidelines of HTA agencies and ministries of health on the use of ceftaroline fosamil in hospitalized adolescents and children over the age of two months ?

Pediatric population

Despite the fact that global production of ceftaroline fosamil began in 2010, the clinical evidence on its use for pediatric CAP is limited to only two (2) trials (File et al, 2012). The three (3) scoped clinical practice guidelines on the management of pediatric CAP **do not include the use of ceftaroline fosamil in their recommendations.**

The 2021 clinical practice guidelines of the Philippine Academy Pediatric Pulmonologists and the Pediatric Infectious Disease Society of the Philippines does not include the use of ceftaroline fosamil for CAP among infants and children aged 3 months to 18 years. Similarly, the use of ceftaroline fosamil for non-severe and severe CAP among children under 10 years old and adolescents is not included in the recommendations of the Omnibus Health Guidelines for Children (2023) and the Omnibus Health Guidelines for Adolescents (2023). Additionally, the latest National Antibiotics Guidelines (2017) does not include ceftaroline fosamil in the recommended antibiotics for infants and children up to five years old with moderate- and high-risk CAP.

OVERALL JUDGMENT

Summary of efficacy and safety outcomes

Pediatric Population

Research Questions	Direction of Judgement
RQ1. *What is the magnitude and severity of community-acquired pneumonia (CAP) among adults, adolescents, and children over the age of two months?*	Significant Burden (high rates of MDR and high ceftriaxone resistance rates in most common pathogens as detected by ARSP)
RQ2.1. *Among hospitalized patients across different ages (i.e., adults, adolescents, and children over the age of two months) with moderate to severe CAP, what is the efficacy and/or effectiveness (i.e., clinical cure rates; all-cause mortality; mortality rate as treatment failure; and length of hospital stay) of ceftaroline fosamil versus non-pseudomonal beta-lactams (i.e., ceftriaxone, cefotaxime, ampicillin/sulbactam) with or without macrolides (i.e., azithromycin, clarithromycin, erythromycin)?*	Inconclusive • Clinical cure rate [EOT] • All cause mortality • Clinical cure rate [TOC]
RQ2.2. *Among hospitalized patients across different ages (i.e., adults, adolescents, and children over the age of two months) with moderate to severe CAP, what is the safety (i.e., adverse events, serious adverse events, discontinuation because of adverse events, and death) of ceftaroline fosamil versus non-pseudomonal beta-lactams (i.e., ceftriaxone, cefotaxime, ampicillin/sulbactam) with or without macrolides (i.e., azithromycin, clarithromycin, erythromycin)?*	Inconclusive • Treatment emergent adverse events • Serious adverse events • Discontinuation due to AEs
RQ2.3. *What are the current guideline recommendations on the general acceptability and use of Ceftaroline fosamil in treating moderate to severe CAP.*	Not included in the recommendation from PIDSP, DOH OHG and DOH NAG

OVERALL CLINICAL JUDGMENT

Pediatric Patients

	Overall Clinical Judgment	Next Steps for Costing Analysis
Option A *[Superior]*	In terms of efficacy/effectiveness, ceftaroline has **superior efficacy/effectiveness** vs. non-pseudomonal beta-lactams with or without macrolides or vancomycin for hospitalized children with moderate to severe CAP. In terms of safety, ceftaroline has **comparable safety** vs. non-pseudomonal beta-lactams with or without macrolides or vancomycin for hospitalized children with moderate to severe CAP	**CUA/CEA + BIA** *CUA= Cost Utility Analysis* *CEA = Cost Effectiveness Analysis* *BIA = Budget Impact Analysis*
Option B *[Non-inferior]*	Ceftaroline has **comparable efficacy/effectiveness and safety** vs. non-pseudomonal beta-lactams with or without macrolides or vancomycin for hospitalized children with moderate to severe CAP	**CMA + BIA** *CMA = Cost Minimization Analysis* *BIA = Budget Impact Analysis*
Option C *[Inferior]*	Ceftaroline has **inferior efficacy/effectiveness and safety** vs. non-pseudomonal beta-lactams with or without macrolides or vancomycin for hospitalized children with moderate to severe CAP	**Do not proceed to Economic Assessment**
Option D *[Not enough evidence]*	There is **limited evidence** in the efficacy/effectiveness and safety of ceftaroline vs. non-pseudomonal beta-lactams with or without macrolides or vancomycin for hospitalized children with moderate to severe CAP. There is a need for further studies to be conducted in order to provide the needed evidence that is responsive to its decision criteria based on the UHC Law.	**Do not proceed to Economic Assessment**

THANK YOU!