Cubicin®/Cubicin® RF (daptomycin) – Expanded indication

- On March 29, 2017, the FDA approved Merck's Cubicin/Cubicin RF (daptomycin) for complicated skin and skin structure infections (cSSSI) in pediatric patients (1 to 17 years of age) caused by susceptible isolates of the following Gram-positive bacteria: *Staphylococcus aureus* (including methicillin-resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae* subsp. *equisimilis*, and *Enterococcus faecalis* (vancomycin-susceptible isolates only).
    - Previously, Cubicin/Cubicin RF was only approved in adult patients for cSSSI.
    - Cubicin/Cubicin RF is also approved for *Staphylococcus aureus* bloodstream infections (bacteremia), including those with right-sided infective endocarditis in adult patients.
    - Cubicin/Cubicin RF is not indicated for the treatment of pneumonia.
    - Cubicin/Cubicin RF is not indicated for the treatment of left-sided infective endocarditis due to *S. aureus*.
    - Cubicin/Cubicin RF is not recommended in pediatric patients younger than one year of age due to the risk of potential effects on muscular, neuromuscular, and/or nervous systems (either peripheral and/or central) observed in neonatal dogs.
- The approval of Cubicin/Cubicin RF's expanded indication was based on a randomized study of 396 pediatric patients aged 1 - 17 years with cSSSI. Patients received Cubicin once daily or standard of care comparator for up to 14 days. Patients could switch to oral therapy after clinical improvement was demonstrated. The clinical success rates were determined by resolution or improvement of symptoms 7 - 14 days after the last dose of therapy (intravenous and oral).
    - The clinical success rates were 88% for Cubicin and 86% for the comparator.
    - Additional support for the use of Cubicin/Cubicin RF in pediatric patients with cSSSI is supported by evidence from adequate and well-controlled studies with Cubicin in adults and with additional data from pharmacokinetic studies in pediatric patients.
- The most common adverse reactions (≥ 2%) with Cubicin/Cubicin RF use in pediatric patients with cSSSI were diarrhea, vomiting, abdominal pain, pruritus, pyrexia, elevated creatinine phosphokinase, and headache.
- The recommended dose of Cubicin/Cubicin RF in pediatric patients with cSSSI is administered once every 24 hours for up to 14 days as follows:

Age Range	Dosing Regimen
12 – 17 years	5 mg/kg infused over 30 minutes
7 – 11 years	7 mg/kg infused over 30 minutes
2 – 6 years	9 mg/kg infused over 60 minutes
1 - < 2 years	10 mg/kg infused over 60 minutes

- Cubicin/Cubicin RF should not be administered by injection over a 2 minute period to pediatric patients.
- Consult Cubicin/Cubicin RF's drug label for the recommended doses for adult patients.