Treatment of Skin and Soft Tissue Infections in the Emergency Department

EVALUATING OMADACYCLINE USE

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Foreword

The ASHP Foundation ("the Foundation") presents this medication-use evaluation (MUE) resource guide in support of ASHP's vision that medication use will be optimal, safe, and effective for all people, all the time.

An advisory panel of experts developed this guide and template that users may customize based on their organizational goals and objectives.

This MUE resource guide can support stewardship efforts to monitor and improve the care of patients. It is not meant to promote or recommend a specific medication or course of treatment.

Background

The American Society of Health-System Pharmacists (ASHP) recently published Guidelines for Conducting Medication-Use Evaluations (MUE).[1] The ASHP guidelines define an MUE as a systematic and interdisciplinary performance improvement method with an overarching goal of optimizing patient outcomes via ongoing evaluation and improvement of medication utilization. Common MUE objectives include promoting optimal medication therapy; improving patient safety; standardizing to reduce variation and waste (including cost minimization); and drug therapy optimization (Appendix A).[1] Drug therapy optimization may include efficient delivery of care (e.g., timely drug administration), effective delivery of care (e.g., desired treatment response or cure), and safe delivery of care (decreased adverse drug reactions). The guidelines also establish a process for identifying and completing an MUE while incorporating the roles and responsibilities of the interdisciplinary team. Conducting an MUE involves the following elements:

- Establishing the MUE goals and objectives
- Defining the specific "investigative" or "medication use" question to be answered
- Prioritizing and selecting the medication(s) and processes for evaluation
- Establishing the ideal or current steps in the process
- Defining measures to evaluate the process, including any current standards
- Creating a process for data collection

An MUE process can focus on a clinical decision-making process (e.g., clinical guidelines for prescribing and the approval process) or a workflow process (e.g., ordering, preparing, dispensing, or monitoring the drug).

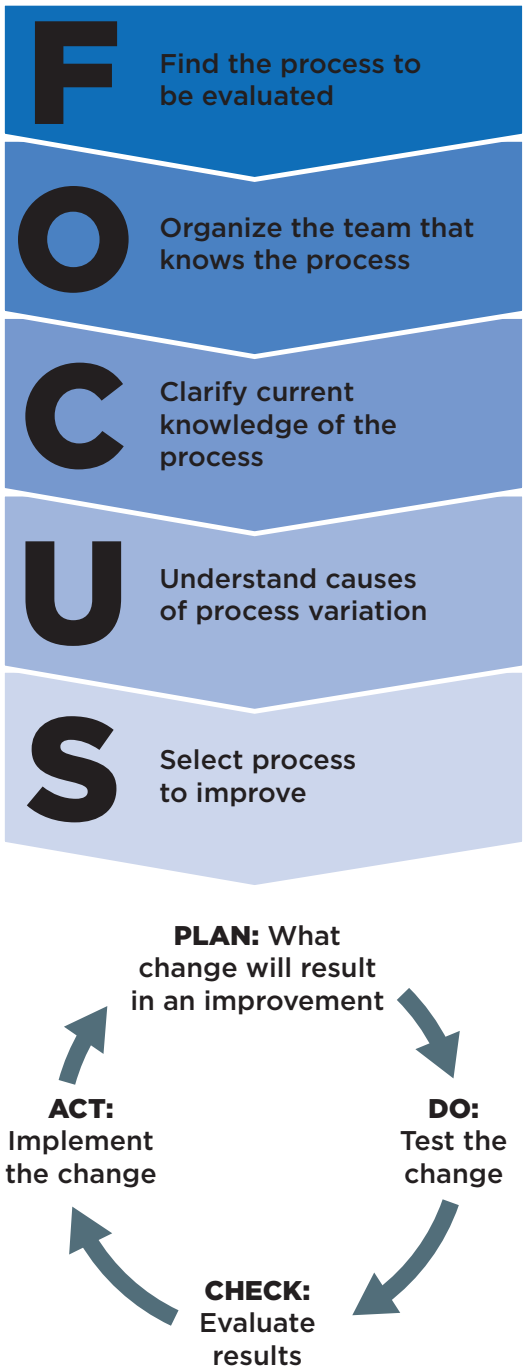
As a performance improvement tool, MUEs can be used when there is uncertainty regarding whether a medication is achieving its intended outcomes, is safe, or is being prescribed according to accepted guidelines. One model that can be applied is the FOCUS-PDCA framework described in the ASHP guidelines. The *ASHP Medication Use Resource Guide: Andexanet Alfa in the Management of Life-Threatening Bleeds in Patients on Direct Factor Xa-Inhibitors* describes an MUE using the FOCUS-PDCA Framework.[2]

MUEs can also be part of a structured or mandated multidisciplinary quality management program that evaluates a medication's overall value (including its place within treatment guidelines), cost-effectiveness, or impact on patient safety. One example of this would be conducting a medication use review of an antibiotic as part of an antibiotic stewardship program (ASP). This resource guide provides a template for developing an MUE for an ASP, specifically the use of a newer antibiotic, omadacycline, approved for the treatment of acute bacterial skin and skin structure infections (ABSSSIs), in the emergency department (ED) and urgent care (UC) setting. The ASHP Foundation facilitated the creation of this MUE template and implementation guide with input from an Advisory Panel (AP) of experts.

Antibiotic Stewardship: The Emergency Department Setting

The goals of antibiotic stewardship are to reduce avoidable adverse events, minimize the emergence of resistance (e.g., through the reduction of unnecessary prescribing and proper duration of therapy), and improve treatment outcomes (e.g., decreased relapse/recurrence, timely treatment with adequate susceptibility).[3] Traditionally, antibiotic stewardship has focused on the inpatient setting. The Centers for Diseases Control and Prevention (CDC) recently published the Core Elements of Outpatient Antibiotic Stewardship.[3] There is a significant opportunity

Figure 1. Elements of the FOCUS-PDCA MUE framework



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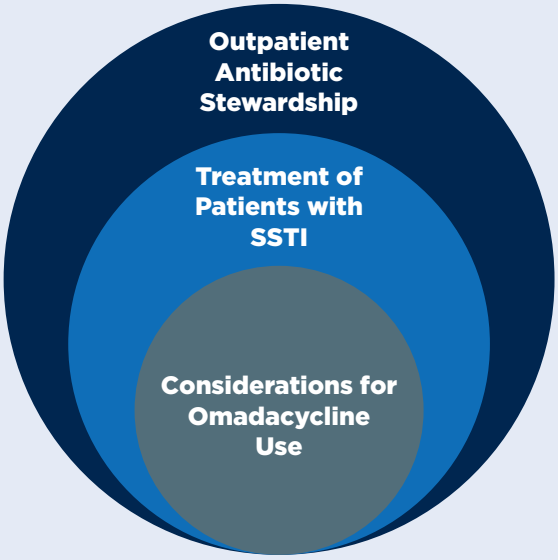
to improve antibiotic use in the outpatient setting, which includes ED and UC visits:

- 85–95% of antibiotics are prescribed in the outpatient setting
- Antibiotic-associated adverse drug events are responsible for almost one in six (16%) ED visits
- At least 28% of antibiotics prescribed in the outpatient setting are unnecessary, meaning no antibiotic was indicated[4,5]

Pharmacist-led outpatient ASPs improve adherence to medication use guidelines for select treatment regimens, including urinary tract infections (UTIs) and skin and soft tissue infections (SSTIs).[6,7] While the goal is to reduce unnecessary antibiotic prescribing, choosing optimal therapy is essential to improving outcomes, reducing adverse events, avoiding multiple or extended courses of therapy, and minimizing the risk of ED visits or hospitalization. For example, it is possible to reduce adverse events when the selection of a regimen considers underlying disease states such as renal insufficiency, and then doses are appropriately adjusted. It is also important to consider potential drug interactions that might result in sub-therapeutic effects or drug toxicity. The prevalence of resistant organisms in the community or in patients who may be immune-compromised or with previous antibiotic exposure is also important to consider when choosing optimal therapy. In addition, ASPs and medication use evaluations can be challenging in the outpatient setting when there are multiple providers, a lack of data integration, discordance between hospital and health plan formularies, and lack of follow-up with the patient, thus, making outcomes difficult to assess. Finally, institution-specific stewardship must define "optimal therapy" by adapting published guidelines to local factors, such as the availability of rapid culture and the patient's ability to access medications in a timely manner.

Defining the Focus of an Antibiotic Stewardship MUE



Treatment of SSTIs: Selecting the Medication Use Question

Monitoring antibiotic prescribing practices and offering regular feedback to clinicians is critical to improving prescribing, decreasing adverse events, and reducing the emergence of antibiotic resistance. When conducting an antibiotic use evaluation, consideration and priority should be given to the following:

- High-risk or high-volume antibiotic use
- High-risk or high-volume infections
- Infections where there are established treatment guidelines
- Infections where there is a high potential for the emergence of resistance
- Infections where there is potential for practice variation (e.g., a new drug approved, the absence of updated guidelines, variation in outpatient formularies)

Monitoring antibiotic use in high-priority conditions can also assess whether an antibiotic was appropriate for the assigned diagnosis, whether the diagnostic criteria were met before assigning an antibiotic-appropriate diagnosis, whether the selected antibiotic was the recommended agent, and whether the dose and duration of the selected antibiotic were correct.[3] The treatment of SSTIs in the emergent or urgent care setting meets several of these priorities. SSTIs are among the top reasons patients come to the ED. In 2018 more than half of patients diagnosed in the ED with "skin and subcutaneous" infections in the US were admitted to the hospital; almost 3 million patients were treated and released.[8,9] Patients treated for SSTIs as part of an ASP often received appropriate antibiotics, had a shorter time for intravenous (IV) to oral therapy conversion, and had fewer treatment complications.[10] Ideally, ASPs can help to determine appropriate therapy for empiric therapy or treatment, given local resistance patterns and considering national guidelines. Other considerations for appropriate antibiotic selection in the outpatient setting when treating SSTIs include the ability to transition from the IV to oral formulation, once-daily dosing, pharmacokinetics that are unaffected by various patient characteristics, a low drug-drug interaction profile, and no requirement for therapeutic monitoring.[11] Omadacycline, the FDA-approved tetracycline antibiotic for treating ABSSSIs, is an ideal candidate for conducting an antibiotic stewardship MUE given some of its characteristics and relatively recent entry into the market.

TIPS AND STRATEGIES: Key Steps for MUEs

A multidisciplinary institutional advisory committee should be convened before initiating the MUE and have the expertise to:

- Confirm or update published guidelines or institution-specific guidelines.
- Identify or refine key processes to assess and question(s) to be answered.
- Select measurable objectives.
- Assist in identifying references (e.g., recently published studies and guidelines).
- Design the MUE by deciding on methodology and selecting the sample population, sample size, and inclusion and exclusion criteria.
- Create a data collection plan and tool.
- Review results, make recommendations for improvement and develop plans to measure post-implementation.[1]

Bringing Together the Team of Experts

In this MUE simulation project, a team of experts was assembled to establish considerations for using omadacycline to treat SSTIs in the emergency department and urgent care setting for patients discharged to home ("treat and release"). While product labeling lists approved indications and specific guidelines for dosing, the most recent Infectious Disease Society of America

(IDSA) guidelines were published in 2014, before omadacyclines entered the market.[12] Therefore, when developing the MUE, the team needed to consider new studies and updated clinical guidelines, outpatient formulary availability, and the drug's place in therapy, given local resistance patterns.

For this simulation, members of the AP (team) were selected with expertise in medication-use evaluations or antibiotic stewardship, particularly in the outpatient and emergency setting. The team also included pharmacists and physicians practicing in infectious diseases or emergency medicine. The team's initial approach was to review current treatment guidelines for managing SSTIs and new evidence published since the 2014 guidelines. They also considered current evidence related to the severity and diagnostic assessment of SSTI, such as the CREST or Enron criteria.[14,15,16,17] The Eron classification is a method of stratifying the severity of patient presentation. After reviewing the most current evidence, the AP discussed where they specifically wanted to focus the MUE, and they decided to conduct an evaluation to answer the question:

Is prescribing oral omadacycline in the emergency department and urgent care setting (when a patient is discharged to home) consistent with institutional guidelines?

Once the focus was narrowed to oral treatment, the AP discussed the potential place in therapy for the new antibiotics (Appendix B). Please note that the panel did not discuss dosing and options for all therapies; therefore, this resource guide will not delve into the choice of antibiotics or doses based on the specific SSTI types; instead, it uses omadacycline as an example and focuses on the appropriate prescribing in this setting. Information on the treatment of SSTIs is available in the literature or from online resources and national guidelines.[12-14] When reviewing any general resources, it is important to note that there may be local differences based on local susceptibility patterns; also, there may be more updated information in the primary literature. Assembling a local team of experts can provide valuable insights into these nuances.

TIPS AND STRATEGIES: Organize the Team

- Consider all key stakeholders and the different perspectives they can bring or how they can support the evaluation.
- Consider approved labeling, build upon current consensus guidelines, review new literature, and refine the MUE to the setting.
- Add stakeholders from support departments, such as finance or quality, to the team.

Reaching Consensus: Considerations for Omadacycline Use

To begin answering the MUE Question, the advisory panel first needed to define when omadacycline prescribing might be considered for treating SSTI in the ED. Omadacycline was unavailable when the 2014 IDSA guidelines were published; however, more recent publications indicate a possible selective role for its use in SSTIs.[13-20] Omadacycline is FDA-approved for adults patients with ABSSSIs (i.e., cellulitis, erysipelas, abscess, or

wound infections without osteomyelitis) including patients with underlying comorbidities such as diabetes.[18] Omadacycline has high activity against *Staphylococcus aureus*, including methicillin-resistant strains, and is active against tetracycline-resistant pathogens. Another possible consideration for omadacycline's place in therapy is that it can be administered orally or intravenously (IV), and its pharmacokinetic profile allows for once-daily dosing.[10,21-22] For example, it might be advantageous to administer an IV dose in the ED with 24-hour observation prior to discharging on oral therapy. Some potential advantages of using omadacycline as an alternative to other available therapies that should be considered include comorbidities or patient-specific factors. For example, omadacycline has not been shown to have renal toxicity, which might be a potential advantage compared to vancomycin in patients with renal insufficiency. Also, unlike linezolid, which labeling warns about the potential to cause serotonin syndrome when administered with selective serotonin reuptake inhibitors (SSRIs), this interaction has not been reported with omadacycline. In addition, omadacycline is associated with a lower risk of *Clostridioides difficile* infection (CDI) compared with other antibiotics, a possible advantage compared to clindamycin, β-lactams, and fluoroquinolones, particularly for elderly patients or those who have previously had CDI.[22] Finally, as with other tetracyclines, omadacycline may be an alternative to those with prior allergic reactions to other antibiotics. Also, omadacycline may interact with food, dairy, and other calcium-containing products and may increase the effects of anticoagulants.

Based on the evaluation of the current literature and discussion within the group, the AP agreed upon the following as guidance for the use of omadacycline in the treatment of SSTIs in the ED setting:

Omadacycline use may be considered for the treatment of SSTIs:

When there are select comorbidities:

- In patients at high risk for or known underlying renal dysfunction
  - Elderly or patients with diabetes
- May be preferred in patients with diabetes
- May be preferred in patients that are immunocompromised
- To avoid CDI, especially in older patients or those with a history of CDI

When there are other patient-specific factors:

- Adherence concerns-once daily oral dosing/ single drug with broad coverage
- For mild or moderate infections, if in an area with high (e.g., >20%) resistance of streptococci to doxycycline
- Patients who have failed prior SSTI antibiotic therapy
- Avoidance of drug interactions
  - Consider omadacycline for patients on selective serotonin reuptake inhibitors (SSRIs) if concerned about possible serotonin syndrome with linezolid
- Patients unable to tolerate alternative therapy (e.g., some patients cannot tolerate high-dose trimethoprim-sulfamethoxazole (TMP/SMX), allergies, or intolerance to vancomycin, TMP-SMX, or *beta*-lactam antibiotics).

Conducting the MUE: Measurement and Data Collection Framework

Every MUE requires a starting point or practice standard as well as process and outcome measures, data elements to collect, and sources for the data. Whether the process is prescribing (e.g., adherence to established guidelines) or dispensing (e.g., the optimal duration of therapy), the "current state" must be determined. The "current state" evaluation for a prescribing process might involve reviewing the medical record and order sets, reaching a consensus on institutional guidelines for prescribing, or reviewing approval documentation (when a formal stewardship process is in place). The "current state" for a preparation and dispensing process can include a review of the existing policies and procedures, dispensing records, and real-time development of a process flow chart (i.e., what was observed in practice versus what is expected). Measurement and data collection strategy will vary depending on the method of data collection: a prospective, concurrent, or retrospective review and what data elements are readily accessible in the electronic health record. After outlining the considerations for omadacycline use and reaching a consensus, the AP mapped out the MUE template and data collection form. Appendix C provides an example data collection framework.

TIPS AND STRATEGIES: Clarify the Process

- When updating organizational guidelines, consider approved labeling, build upon current consensus guidelines, review new literature, and refine it to the setting.
- As a group, review the current processes and identify key process elements and desired measurable outcomes.
- Identify key process elements and desired, measurable outcomes, relevant and easy to obtain or collect.

Improving Processes: Implement Tests of Change

Once the data is collected, it should be analyzed and presented to the team for review and discussion. Consider exceptions and outliers and whether the variance is reasonable (e.g., a unique exception or new study). In this case, there may need to be a change to the process design and whether to include the variance as an "acceptable" variation. Sometimes unclear or unknown steps are identified, called process "clouds." Examples of "clouds" are patients who cannot be contacted for follow-up, missing diagnostic tests (e.g., culture and susceptibility) results, or patients who did not take the medication prescribed (e.g., insurance did not cover the medication). While the AP did not collect actual data during this simulation, they contributed experience from their organizations to develop a sample framework, including process and outcome performance measures. It is best to be transparent in the data analysis and presentation, seek and incorporate input from the team, and ensure agreement when interpreting results. Upon identifying variances, the team should discuss process improvement options. Ideas can occur through brainstorming and networking with

other stakeholders or professional colleagues. Questions to ask during this process include:

- Are there ways to reduce the variation (such as delays in receiving therapy due to prescription denial)?
- Are there ways to reduce waste (such as patient returns to the ED)?
- Are there "clouds" in the process where it is unclear what has occurred?
- How have other organizations addressed these issues?
- Are there best practices that could be implemented?

The next phase of the process improvement is implementing the test(s) of change identified by the MUE team and evaluating the change, known as the Plan/Do/Check/Act (PDCA) cycle. Team members should work together to develop a specific solution and timeline for implementation and any education or information system changes that need to be made (Plan). It is ideal to have one person identified as the champion for the process improvement. Sometimes it is best to study the change in one area before moving it out to the organization (Do). Once implemented, the change should be measured, and the results evaluated (Check). Successful changes should be scaled and reassessed to ensure the gain has been sustained or to update the process or guideline (Act). The results of an MUE and proposed or implemented changes and improvements from those changes should be shared with relevant organization committees.

Conclusion

A multidisciplinary team applied the FOCUS-PDCA framework in a simulation to develop an MUE assessing the use of oral omadacycline in the emergency department for patients who will be discharged home. By applying the ASHP guidelines as an outpatient antibiotic stewardship initiative and customizing the template in this resource guide, organizations can optimize medication use, reduce process variation, minimize adverse events, and improve patient outcomes.

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Disclosures

Available by contacting the ASHP Foundation.

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Appendix A: Tips and Strategies for Conducting an MUE Using the Focus Framework[1]

Step	Indicator
Prescribing	• Publication of guidelines that may change treatment patterns • New organizational interventions to improve medication therapy, such as changes to protocols or formularies • Changes to pharmacy clinical services to improve medication therapy • Introduction of or changes in quality indicators
Dispensing	• Signs of process failures, such as wasted medication or delayed medication delivery • Incorrect medication preparation • Dosing that requires clinician preparation or compounding • Ensuring compliance with regulatory requirements (e.g., Joint Commission, FDA, USP)
Administration	• Medication misadventures related to medication delivery systems • Multiple medication concentrations, units of measure, or infusion rates
Monitoring	• Adverse events, including medication errors, preventable adverse drug reactions, and toxicity • Signs of treatment failures • Patient/family dissatisfaction or deterioration of the quality of life attributable to drug therapy
Systems Management and Control	• Risk Evaluation Mitigation (REMS) programs, restricted distributions channels, or other access challenges • Drug shortages requiring replacement or therapeutic substitution • Timeliness of administration • Diversion of medications and materials • Lack of standardization or confusion within the medication-use process • Changes in contracts, cost, or spending on drugs • Organizational priorities such as budget constraints or cost-saving initiatives

Appendix B: Oral Antibiotics Used to Treat Mild/Moderate Skin and Soft Tissue Infections[1] in the Emergency Department Setting[2]

Non-Purulent	Purulent[3]		
Cellulitis/Erysipelas (Usually *Streptococcus pyogenes*/ Group A Strep)	Furuncle/Carbuncle/Abscess (Usually *Staphylococcus aureus*)		
	Empiric Therapy	**Defined Therapy-MRSA**	**Defined Therapy-MSSA**
Penicillin VK	TMP/SMX	TMP/SMX	Cephalexin
Cephalexin	Doxycycline	Doxycycline	Dicloxacillin
Dicloxacillin	Omadacycline[4]	Linezolid	Amoxicillin/clavulanate[3]
Clindamycin		Omadacycline[4]	
		Tedizolid[4]	

1 Oral antibiotics for mild or moderate infection without systemic signs of infection (e.g., fever, tachycardia, tachypnea, increased white blood cells). Mild purulent infections without systemic signs of infection may be treated with incision and drainage without antibiotics.
2 Adapted with permission of K. LaPlante from Providence Veterans Affairs Medical Center Antimicrobial Guide Empiric Therapy, 5th edition.
3 Drug therapy with incision and drainage
4 Diabetic foot infections, no suspicion of *P. aeruginosa*

Appendix C. MUE Template and Data Collection Framework for Omadacycline Medication Use Evaluation[1]

PATIENT DEMOGRAPHICS

- ☐ **Medical record number**
- ☐ **Date of birth**
- ☐ **Height**
- ☐ **Weight**
- ☐ **Allergies**
- ☐ **Creatinine clearance**
- ☐ **Encounter date**
- ☐ **Temperature**

INDICATION FOR ANTIBIOTIC TREATMENT

- ☐ **Mild (>5cm) infection**
  - Purulent
  - Non-purulent
- ☐ **Moderate infection**
  - Purulent
  - Non-purulent
- ☐ **Severe Infection**
  - Purulent
  - Non-purulent
- ☐ **Disposition**
  - ☐ Patient discharged on antibiotics
    - IV
    - PO
  - ☐ Patient in observation, then discharged
    - IV
    - PO
  - ☐ Patient admitted on antibiotics
    - IV
    - PO
- ☐ **I&D**
- ☐ **C&S obtained Y/N (date)**
  - Organism
  - Susceptibility

TIPS AND STRATEGIES

Identify processes based on indicators of need: improve safety, promote optimal therapy, standardize to reduce process variation, cost-benefit, and meet compliance standards.

CONSIDERATIONS FOR OMADACYCLINE

- ☐ **Resistance patterns**
  - There is documented community resistance to streptococci (>20%)
- ☐ **Comorbidities**
  - ☐ In high-risk patients/patients with diabetes, obese, elderly, underlying renal dysfunction
    - Patient with diabetes
    - Immunocompromised patient
    - Obese patient
    - Patient with underlying renal insufficiency
  - ☐ *C. difficile* avoidance, especially in older patients, history of *C. difficile* associated-diarrhea
- ☐ **Other considerations**
  - Adherence concern-once daily oral dosing/single drug with broad coverage
  - For mild infections, if in an area with high (e.g., >20%) resistance of *streptococci* to doxycycline

1 This is an example set of MUE criteria. Each institution should establish guidelines and MUE criteria appropriate to the setting.

- Patients who have failed prior therapy
- Avoidance of drug interactions
  - Consider omadacycline for patients on SSRIs if concerned about possible serotonin syndrome w/linezolid
- Patient not able to tolerate alternative therapy (e.g., some patients can't tolerate TMP/SMX)

PROCESS MEASURES

☐ **Prescriber:**

☐ **Dose omadacycline prescribed:**

☐ In ED:
- Patient is able to take PO
- Loading dose - 200 mg by IV infusion over 60 minutes on day 1; 100 mg by IV infusion over 30 minutes, twice on day 1; OR 450 mg orally once a day on day 1 and day 2
- Maintenance Dose - 100 mg by IV infusion over 30 minutes once daily, or 300 mg orally once daily for 7-14 days
- Other:
- IV administered in ED
- IV administered in an infusion center
- Oral administered in the ED and prescribed at discharge

☐ **If Oral prescribed at discharge:**
- Omadacycline dispensed from ED
- Prescription provided to the patient upon discharge
- Loading dose administered
  - 450 mg (three 150 mg tablets) once a day on days 1 and 2
- 300 mg (two 150 mg tablets) once a day, not to exceed 14 total days of treatment (i.e., IV and oral treatment days combination)

☐ **Follow-up**

☐ Call placed to primary care physician

☐ Call placed to the patient within the designated timeframe
- within 24 hours
- within 72 hours
- other:

☐ Rx filled within 24 hours
- Patient took the drug for the duration prescribed

☐ If Rx not filled:
- Prescription coverage denied/did not fill the prescription
- Prescription coverage denied/alternate therapy prescribed

☐ Patient continued to take the drug as prescribed

☐ Duration of therapy (total doses/number of days)

☐ Patient did not continue to take the drug as prescribed
- Drug discontinued due to side effects
- Therapy change required based on C&S
- Therapy change required due to lack of response/resolution

TIPS AND STRATEGIES

Try to have data collection as automated as possible (e.g., build fields/queries into the medical record or identify easily extractable measures) from existing databases.

OUTCOME MEASURES

☐ **Outcomes**

☐ Therapy failure
- Recurrence/reinfection (different pathogen within 30 days)
- Relapse (same pathogen within 30 days)
- Return to ED/urgent care
- Hospital admission

☐ Adverse event; describe:

☐ Therapy change; describe:

About the ASHP Foundation

The ASHP Foundation was established in 1968 by ASHP as a nonprofit, tax-exempt organization. As the philanthropic arm of ASHP, the Foundation shares ASHP's vision that medication use will be optimal, safe, and effective for all people all of the time. Our mission is to support ASHP by advancing the professional practice of pharmacists and the pharmacy workforce by funding research and education that improves health outcomes through optimal, safe, and effective medication use. To learn more about the Foundation's programs, visit **ashpfoundation.org**.

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