

Mycoplasma genitalium Treatment Failure Registry

CASE REPORT FORM

The purpose of this form is to collect clinical information on cases of *Mycoplasma genitalium* that fail antibiotic therapy

Public reporting burden of this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: OMB-PRA (0920-New)

All reported information will be maintained in the strictest confidence. Questions? Contact xxx at XXX@cdc.gov

Confidentiality Note: The information in this form includes confidential information intended only for the use of the individual or entity named below. If the reader of this form is not the intended recipient, you are hereby notified that any dissemination, distribution or copy of this form is strictly prohibited and may result in civil and criminal penalties under federal law. If you have received this form in error, please immediately notify us immediately at the number above.

PLEASE COMPLETE BY / / and fax to our confidential fax line (xxx)xxx-xxxx.

PROVIDER INFORMATION:

Provider Name	Provider Phone #	Provider Fax #	
Provider Email Address	Practice/Clinic Name		
Address	City	State	Zip

PATIENT UNIQUE IDENTIFIER* (First Initial, Last initial, 2-digit year of birth, last 4 digits of Medical Record Number)
Example: John Smith, born 1973, MRN 1234567 = JS734567

PATIENT AGE: _____ **PATIENT PREVIOUSLY REPORTED TO THE REGISTRY?** Yes No

PATIENT DEMOGRAPHIC INFORMATION:

<p>1. Race (check all that apply)</p> <input type="checkbox"/> Unknown <input type="checkbox"/> White <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> American Indian / Alaska Native <input type="checkbox"/> Native Hawaiian / Other Pacific Islander <input type="checkbox"/> Other _____ <p>2. Ethnicity</p> <input type="checkbox"/> Unknown <input type="checkbox"/> Hispanic / Latino <input type="checkbox"/> Not Hispanic / Latino	<p>3a. Sex assigned at birth</p> <input type="checkbox"/> Male <input type="checkbox"/> Female <p>3b. Gender identity</p> <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Transgender female <input type="checkbox"/> Transgender male <input type="checkbox"/> Gender non-binary <input type="checkbox"/> Unknown
<p>4. Gender of sex partners in past year (check all that apply)</p> <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Transgender female <input type="checkbox"/> Transgender male <input type="checkbox"/> Gender non-binary <input type="checkbox"/> Unknown	<p>5. HIV Status</p> <input type="checkbox"/> HIV-positive <input type="checkbox"/> HIV-negative <input type="checkbox"/> Unknown/Never tested

DIAGNOSTICS/ TREATMENT

Indication for M. genitalium testing (check all that apply): 1) Symptoms: Urogenital (e.g., discharge, dysuria) Anorectal (tenesmus, discharge, pain) Pelvic/abdominal (pain, dyspareunia) 2) Clinical Syndrome (w/ objective findings): Urethritis (documented discharge or pyuria) Cervicitis (discharge, friability, + swab test) PID Proctitis Other _____

<p>M. genitalium diagnosis confirmed with nucleic acid amplification test?</p> <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<p>Laboratory performing M. genitalium testing. (e.g., Quest, LabCorp, name of hospital, etc)</p> <p>_____</p>	<p>Testing for macrolide resistance performed?</p> <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, mutation detected? <input type="checkbox"/> Yes <input type="checkbox"/> No
---	---	---

Testing for fluoroquinolone resistance performed? Yes No
If yes, mutations detected: S83I parC unspecified

<p>Date of initial treatment initiation</p> <p>____/____/____ <input type="checkbox"/> Unknown</p>	<p>Date of 2nd course treatment initiation</p> <p>____/____/____ <input type="checkbox"/> Unknown</p>	<p>Date of 3rd course treatment initiation</p> <p>____/____/____ <input type="checkbox"/> Unknown</p>
<p>Initial treatment prescribed (check all that apply), and dose/frequency/duration (e.g., doxycycline 100 mg po BID x 7 days)</p> <input type="checkbox"/> Azithromycin _____ x days <input type="checkbox"/> Doxycycline _____ x days <input type="checkbox"/> Moxifloxacin _____ x days <input type="checkbox"/> Minocycline _____ x days <input type="checkbox"/> Other _____ x days	<p>Second treatment prescribed (check all that apply), and dose/frequency/duration</p> <input type="checkbox"/> Azithromycin _____ x days <input type="checkbox"/> Doxycycline _____ x days <input type="checkbox"/> Moxifloxacin _____ x days <input type="checkbox"/> Minocycline _____ x days <input type="checkbox"/> Other _____ x days	<p>Third treatment prescribed (check all that apply), and dose/frequency/duration</p> <input type="checkbox"/> Azithromycin _____ x days <input type="checkbox"/> Doxycycline _____ x days <input type="checkbox"/> Moxifloxacin _____ x days <input type="checkbox"/> Minocycline _____ x days <input type="checkbox"/> Other _____ x days

Response to initial therapy (check all that apply) <input type="checkbox"/> Persistent symptoms (subjective only) <input type="checkbox"/> Persistent symptoms (subjective) plus objective findings (e.g. discharge, +urine dip, elevated WBC) <input type="checkbox"/> Positive NAAT post treatment	Response to second therapy (check all that apply) <input type="checkbox"/> Resolution of symptoms <input type="checkbox"/> Persistent symptoms (subjective only) <input type="checkbox"/> Persistent symptoms (subjective & objective findings, e.g., discharge, +urine dip, elevated WBC) <input type="checkbox"/> Positive NAAT post treatment	Response to third therapy (check all that apply) <input type="checkbox"/> Resolution of symptoms <input type="checkbox"/> Persistent symptoms (subjective only) <input type="checkbox"/> Persistent symptoms (subjective and objective findings, e.g., discharge, +urine dip, elevated WBC) <input type="checkbox"/> Positive NAAT post treatment
Date of 4th course treatment initiation ____ / ____ / ____ <input type="checkbox"/> Unknown	Date of 5th course treatment initiation ____ / ____ / ____ <input type="checkbox"/> Unknown	Date of 6th course treatment initiation ____ / ____ / ____ <input type="checkbox"/> Unknown
Fourth treatment prescribed (check all that apply), and dose/frequency/duration <input type="checkbox"/> Azithromycin _____ x days <input type="checkbox"/> Doxycycline _____ x days <input type="checkbox"/> Moxifloxacin _____ x days <input type="checkbox"/> Minocycline _____ x days <input type="checkbox"/> Other _____ x days	Fifth treatment prescribed (check all that apply), and dose/frequency/duration <input type="checkbox"/> Azithromycin _____ x days <input type="checkbox"/> Doxycycline _____ x days <input type="checkbox"/> Moxifloxacin _____ x days <input type="checkbox"/> Minocycline _____ x days <input type="checkbox"/> Other _____ x days	Sixth treatment prescribed (check all that apply), and dose/frequency/duration <input type="checkbox"/> Azithromycin _____ x days <input type="checkbox"/> Doxycycline _____ x days <input type="checkbox"/> Moxifloxacin _____ x days <input type="checkbox"/> Minocycline _____ x days <input type="checkbox"/> Other _____ x days
Response to fourth therapy (check all that apply) <input type="checkbox"/> Resolution of symptoms <input type="checkbox"/> Persistent symptoms (subjective only) <input type="checkbox"/> Persistent symptoms (subjective and objective findings, e.g., discharge, +urine dip, elevated WBC) <input type="checkbox"/> Positive NAAT post treatment	Response to fifth therapy (check all that apply) <input type="checkbox"/> Resolution of symptoms <input type="checkbox"/> Persistent symptoms (subjective only) <input type="checkbox"/> Persistent symptoms (subjective and objective findings, e.g., discharge, +urine dip, elevated WBC) <input type="checkbox"/> Positive NAAT post treatment	Response to sixth therapy (check all that apply) <input type="checkbox"/> Resolution of symptoms <input type="checkbox"/> Persistent symptoms (subjective only) <input type="checkbox"/> Persistent symptoms (subjective and objective findings, e.g., discharge, +urine dip, elevated WBC) <input type="checkbox"/> Positive NAAT post treatment
PARTNER TREATMENT		
Does patient have a primary sexual partner? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown If yes, was the primary partner symptomatic? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Was the primary partner treated? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown If yes, was the primary partner examined by you or another clinician prior to treatment? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		
Partner treatment prescribed (check all that apply), and dose/frequency/duration <input type="checkbox"/> Azithromycin _____ x days <input type="checkbox"/> Doxycycline _____ x days <input type="checkbox"/> Moxifloxacin _____ x days <input type="checkbox"/> Minocycline _____ x days <input type="checkbox"/> Other _____ x days	Partner response to therapy (Check all that apply) <input type="checkbox"/> Resolution of symptoms <input type="checkbox"/> Persistent symptoms (subjective only) <input type="checkbox"/> Persistent symptoms (subjective and objective findings, e.g., discharge, +urine dip, elevated WBC) <input type="checkbox"/> Positive NAAT post treatment <input type="checkbox"/> Unknown, partner not examined If partner has persistent symptoms or NAAT following therapy, please complete a separate case report form for the partner.	
Notes: 		