



# CLINICAL GUIDELINES PROGRAM

NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE | HIV · HCV · SUBSTANCE USE · LGBT HEALTH

## Guidance on Screening, Diagnosis, and Treatment of *Mycoplasma genitalium*

*Lead authors: Daniela E. DiMarco, MD, MPH<sup>1</sup>, and Marguerite A. Urban, MD, with the Medical Care Criteria Committee*

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<sup>1</sup> University of Rochester School of Medicine and Dentistry, Infectious Diseases Division



# Guidance on Screening, Diagnosis, and Treatment of *Mycoplasma genitalium*

## Purpose of This Guidance

This guidance on the screening, diagnosis, and treatment of *Mycoplasma genitalium* infection was developed by the New York State Department of Health (NYSDOH) AIDS Institute (AI) Clinical Guidelines Program. By addressing the care of adults with and without HIV who have acquired sexually transmitted *M. genitalium*, this guidance aims to accomplish the following:

- Provide clinicians with recommendations on screening and diagnostic testing and highlight common clinical syndromes.
- Review treatment regimens with demonstrated activity against *M. genitalium*.
- Integrate current evidence-based clinical recommendations and expert advice regarding testing and treatment of *M. genitalium* infection.

The literature on this topic and the disease epidemiology are evolving rapidly. To prepare this guidance, the authors conducted a literature search through MEDLINE, reviewed conference abstracts from the 2019 STI & HIV World Congress and the 2019 Conference on Retroviruses and Opportunistic Infections, and reviewed guidelines published from the U.S. Centers for Disease Control and Prevention; International Union Against Sexually Transmitted Infections; British Association for Sexual Health and HIV; Australian Society for HIV, Viral Hepatitis and Sexual Health Medicine; and Public Health Agency of Canada.

**An emerging cause of sexually transmitted infections (STIs):** *M. genitalium*, a bacterium discovered in the 1980s [Tully, et al. 1981] infects epithelial cells of the urogenital tract [McGowin and Totten 2017]. The organism is now recognized as an emerging cause of STIs worldwide [Tien, et al. 2019] and has specifically been linked to urethritis [Horner PJ, et al. 1993; Horner PJ and Martin 2017], cervicitis [Manhart, et al. 2003], and pelvic inflammatory disease [Haggerty, et al. 2008; Totten, et al. 2008; Bjartling, et al. 2012]. Some studies have raised concerns about associations between *M. genitalium* infection and infertility and pregnancy complications, such as preterm delivery, but there is a paucity of high-quality evidence on these topics [Oakeshott, et al. 2004; Hitti, et al. 2010; Taylor-Robinson and Lamont 2011; Lis, et al. 2015; Wiesenfeld and Manhart 2017]. Treatment of *M. genitalium* infection is challenging in an era of increasing antimicrobial resistance across multiple drug classes. The availability of nucleic acid amplification tests approved by the U.S. Food and Drug Administration raises the possibility of increased detection of *M. genitalium* infection, leading to increased treatment with antibiotics, and potentially, more widespread multidrug resistance [Singh and Manhart 2020].

**Prevalence of *M. genitalium* infection:** In the early 2000s, prevalence estimates suggested that *M. genitalium* infection was more common than gonorrheal infections but less common than chlamydial infections [Manhart, et al. 2007]. Subsequent studies demonstrated that prevalence rates of *M. genitalium* infection vary by population and clinical setting, with general population estimates ranging between <1% and 4% worldwide, and rates among individuals with STIs reported to be as high as 38% [Casin, et al. 2002; Manhart, et al. 2007; Baumann, et al. 2018]. Although these ranges are based on data from multiple countries and populations and include a mix of symptomatic and asymptomatic individuals, most reports suggest that asymptomatic infection is common [Manhart, et al. 2007; Huppert, et al. 2008; Gesink, et al. 2016]. Coinfection with other STIs, such as *Chlamydia trachomatis* or *Neisseria gonorrhoeae* infection can occur [Hooton, et al. 1988; Mena L, et al. 2002; Huppert, et al. 2008; Gaydos C, et al. 2009; Harrison, et al. 2019].

## Risk Factors and Clinical Syndromes

**Risk factors for infection:** Risk factors for infection with *Mycoplasma genitalium* include tobacco use [Manhart, et al. 2003; Balkus, et al. 2018], multiple sex partners [Manhart, et al. 2003; Manhart, et al. 2007; Crowell, et al. 2019], vaginal sex [Manhart, et al. 2007], black race [Manhart, et al. 2007], younger age ( $\leq 22$  years) in cisgender women [Manhart, et al. 2003; Mobley, et al. 2012], and HIV infection [Lusk, et al. 2011; Crowell, et al. 2019].

Transmission is presumed to occur through mucosal contact during penile-vaginal and penile-anal sex, as demonstrated by concordance between partners [Totten, et al. 2008; Cina, et al. 2019]. There is no current evidence of oral-genital transmission.

**Associated clinical syndromes:** Although asymptomatic infection is commonly reported, *M. genitalium* infection has been associated with the clinical syndromes of urethritis, cervicitis, and pelvic inflammatory disease (PID). In cisgender women, *M. genitalium* has been detected in urine [Gaydos CA, et al. 2019], vaginal, and cervical specimens, as well as endometrial tissue samples [Cohen, et al. 2005; Haggerty, et al. 2006]. In cisgender men, *M. genitalium* has been detected in anorectal and urethral samples [Maeda, et al. 1998; Crowell, et al. 2019]. At present, there is insufficient evidence that *M. genitalium* is a primary cause of proctitis and no evidence that it is a cause of pharyngitis or epididymo-orchitis.

Evidence is strong that *M. genitalium* is a causative agent of urethritis and persistent or recurrent urethritis in cisgender men [Totten, et al. 2001; Wikstrom and Jensen 2006; Horner PJ and Martin 2017]. Symptoms of urethritis in this group have been described as milder than those of gonococcal urethritis and similar to those of *Chlamydia trachomatis* urethral infection [Mena L, et al. 2002]. In a study among heterosexual men at an STD clinic in Seattle, Washington, *M. genitalium* was found in 22% of participants with nongonococcal urethritis and 4% of controls. In a multivariate analysis controlling for multiple factors, including prior urethritis, *M. genitalium* was associated with a more than 6-fold increase in the risk of urethritis [Totten, et al. 2001].

Several studies conducted in STI clinics in the United States and internationally have found statistically significant associations between detection of *M. genitalium* and cervicitis, independent of *C. trachomatis* infection, with a Seattle study noting a 3-fold increase in risk for mucopurulent cervicitis [Manhart, et al. 2003; Gaydos C, et al. 2009; Lusk, et al. 2011; Bjartling, et al. 2012]. In a cohort of women with HIV in New Orleans, Louisiana, cure of *M. genitalium* infection was associated with resolution of histologic markers of cervical inflammation, suggesting this pathogen was the cause of cervicitis in these women [Dehon, et al. 2016].

A 2015 meta-analysis found a statistically significant association between *M. genitalium* infection and an increased risk of both cervicitis and PID, even when accounting for coinfections with other STIs [Lis, et al. 2015]. *M. genitalium*-associated PID symptoms may be more indolent and chronic than gonococcal disease [Short, et al. 2009].

## Laboratory Testing

### RECOMMENDATIONS

#### Laboratory Testing

- Clinicians should not routinely screen for *Mycoplasma genitalium* in asymptomatic individuals. (A3)
- When testing is indicated, clinicians should use nucleic acid amplification testing (NAAT) to diagnose *M. genitalium*, with resistance testing if available. (A3)

**Laboratory tests:** *M. genitalium* bacteria have no cell wall and can take months to grow in culture; thus, traditional methods of diagnosis with gram stain or culture are not useful. Diagnosis was difficult until molecular tests, such as NAAT, became available. NAAT is the preferred, U.S. Food and Drug Administration (FDA)-approved diagnostic method for *M. genitalium* infection. The FDA-approved tests currently available for detection of *M. genitalium* are the Aptima™ *Mycoplasma genitalium* Assay (Hologic, Inc) and the cobas® TV/MG Assay (Roche Diagnostics).

Molecular tests that detect both *M. genitalium* and antibiotic-associated resistance mutations are available in some countries. These combination tests are not currently commercially available in the United States but are anticipated to become available in the near future. At present, resistance assays are most useful in determining macrolide resistance. The association of certain resistance mutations with clinical treatment failure is inconsistent, particularly for quinolone antibiotics [Conway, et al. 2019]. However, resistance testing has been demonstrated as a clinically useful tool to guide treatment, resulting in high cure rates, as evidenced by the resistance-guided antimicrobial therapy model [Durukan, et al. 2019] described in more detail in the section on *Treatment* in this guideline. As with other infections associated with emerging antibiotic resistance, resistance testing may help minimize use of broader spectrum antibiotics with greater potential for adverse effects and improve likelihood of treatment success.

**Diagnostic testing:** Diagnostic testing may be considered for individuals with urethritis, cervicitis, or pelvic inflammatory disease (PID). Some experts advise that diagnostic testing for *M. genitalium* be performed only in individuals with symptomatic urethritis, cervicitis, or PID [ASHA 2018; Soni, et al. 2019]; others advise that testing be performed only in

those with negative gonorrhea and chlamydia test results or who do not respond to first-line empiric treatment [Jensen, et al. 2016; Expert Working Group 2017]. Nonresponse to first-line treatment increases the index of suspicion for *M. genitalium* as a causative agent. Reinfection from untreated sexual partners and infection with other STIs such as *Trichomonas vaginalis* or herpes simplex virus are important to include in the differential diagnosis for individuals with recurrent or persistent STI syndromes.

**Specimen collection:** Acceptable specimen types for *M. genitalium* testing include first-void urine and swabs from the vagina, endocervix, cervix, or penile urethra/urethral meatus [Hologic Inc. 2017; Gaydos CA, et al. 2019]. Self-collected specimens are acceptable for vaginal, urine, and urethral meatus sites, although swabs from the urethral meatus have <90% sensitivity [Hologic Inc. 2017; Gaydos CA, et al. 2019]. There is insufficient evidence to recommend extragenital testing for *M. genitalium* in any population. For cisgender women, vaginal swabs are preferred over urine specimens because of greater sensitivity [Mobley, et al. 2012; Gaydos CA, et al. 2019]; for cisgender men, urine specimens are preferred over urethral meatus swabs but have sensitivity comparable to that of traditional urethral swabs [Gaydos CA, et al. 2019]. There is currently no published evidence to support a preferred testing site or type of specimen in individuals who have a neovagina or neopenis.

**Screening:** Currently available evidence *does not* support routine screening for *M. genitalium* in asymptomatic individuals or in any specific population [Golden, et al. 2017; Horner PJ and Martin 2017]. Prevalence estimates of *M. genitalium* in the general population are low, antimicrobial resistance is increasing, and treatment options are limited [Golden, et al. 2017; Horner PJ and Martin 2017; Baumann, et al. 2018; Fernandez-Huerta, et al. 2019].

## Treatment

### RECOMMENDATIONS

#### Treatment

- Clinicians should prescribe treatment with oral moxifloxacin 400 mg daily for 7 to 14 days for individuals with confirmed cases of symptomatic *Mycoplasma genitalium* infection. (B2)
- Clinicians should consider using doxycycline for empiric treatment of persistent or recurrent urethritis or cervicitis while awaiting *M. genitalium* test results, to facilitate lead-in to a 2-step treatment approach. (B2)

**General considerations:** Azithromycin, doxycycline, and moxifloxacin are the most frequently used antibacterial agents for *M. genitalium* treatment (Table). Single-dose azithromycin has been a standard treatment for *M. genitalium* infection [Mena LA, et al. 2009; Schwebke, et al. 2011]; however, there is recent evidence of emerging macrolide resistance and treatment failure associated with the single 1 g oral dose [Manhart, et al. 2013; Gesink, et al. 2016; Horner P, et al. 2018]. Early reports of superior cure rates with an extended course of azithromycin have not been confirmed in more recent studies [Anagrius, et al. 2013; Horner P, et al. 2018]. Prevalence of macrolide-associated resistance mutations is now >50% in many areas and was recently found to be >62% in a sexually transmitted infection (STI) clinic population in the United States [Bachmann, et al. 2019]. A 2015 review of the literature noted that treatment efficacy for both azithromycin and doxycycline has been declining [Manhart, et al. 2015].

Like azithromycin, moxifloxacin had documented cure rates approaching 100%, but in the last decade, that number has fallen below 90% with monotherapy in some studies [Manhart, et al. 2015; Li, et al. 2017]. In the 2015 review noted above, levofloxacin and ofloxacin had lower cure rates than fourth-generation quinolones (including moxifloxacin, gatifloxacin, and sitafloxacin) [Manhart, et al. 2015]. A meta-analysis of primarily observational studies compared efficacy of 7- and 10-day treatment durations for moxifloxacin and found no significant difference [Li, et al. 2017]. For pelvic inflammatory disease (PID) related to *M. genitalium* or in the PID clinical syndrome in general, a 14-day course of moxifloxacin treatment was found to be effective [Ross, et al. 2006; Judlin, et al. 2010; Latimer, et al. 2019a; Ovens, et al. 2019]. Because of emerging resistance overall and a lack of treatment alternatives, moxifloxacin has not been recommended for first-line empiric use in existing international guidelines [Jensen, et al. 2016; Expert Working Group 2017; ASHA 2018; Soni, et al. 2019].

The table below summarizes current treatment options.

<b>Table: Antimicrobial Treatment Regimens for <i>Mycoplasma genitalium</i> Infection</b>	
<b>Oral Regimens</b>	<b>Considerations</b>
Moxifloxacin 400 mg daily for 7 to 14 days [a]	<ul style="list-style-type: none"> <li>Recommended by this committee for symptomatic, laboratory-confirmed <i>M. genitalium</i> infection.</li> <li>Consider for use after failed empiric therapy for STI syndromes when diagnostic testing for <i>M. genitalium</i> is not available and when infection with <i>Chlamydia trachomatis</i>, <i>Trichomonas vaginalis</i>, or other STIs has been excluded or is unlikely.</li> <li>Moxifloxacin is generally not recommended for pregnant individuals. See <i>Special Populations &gt; Pregnant Patients</i>.</li> </ul>
Azithromycin 1 g as a single dose <i>OR</i> 500 mg on day 1, followed by 250 mg daily on days 2, 3, 4, and 5	<ul style="list-style-type: none"> <li>High rates of resistance.</li> <li>Single-dose azithromycin was considered superior to doxycycline [Mena LA, et al. 2009; Schwebke, et al. 2011]; however, the prevalence of resistance is now &gt;50% in most areas [Bachmann, et al. 2019].</li> <li>Only regimen available in the United States that does not contain drugs contraindicated in pregnancy.</li> </ul>
Doxycycline 100 mg twice daily for 7 days, followed by azithromycin 1g on day 1, then 500 mg daily on days 2, 3, and 4	<ul style="list-style-type: none"> <li>Two-step regimen when macrolide resistance is NOT suspected or confirmed [b].</li> <li>Not for persistent or recurrent syndromes.</li> <li>Doxycycline is generally not recommended for pregnant individuals. See <i>Special Populations &gt; Pregnant Patients</i>.</li> </ul>
Doxycycline 100 mg twice daily for 7 days, followed by moxifloxacin 400 mg daily for 7 to 14 days [a]	<ul style="list-style-type: none"> <li>Two-step regimen when there is concern for macrolide resistance [b].</li> <li>Resistance is more likely among MSM and individuals with previous exposure to azithromycin [Bercot, et al. 2019; Furegato, et al. 2019; Li, et al. 2020].</li> <li>Doxycycline is generally not recommended for pregnant individuals. See <i>Special Populations &gt; Pregnant Patients</i>.</li> </ul>
Pristinamycin 1 g 4 times daily for 10 days	<ul style="list-style-type: none"> <li>An option for macrolide and moxifloxacin treatment failure.</li> <li>Not currently available in the United States or Canada.</li> </ul>
<p><b>Abbreviations:</b> MSM, men who have sex with men; PID, pelvic inflammatory disease; STI, sexually transmitted infection.</p> <p><b>Notes:</b></p> <p>a. A 14-day regimen containing moxifloxacin is preferred for treatment of PID [Ross, et al. 2006; Judlin, et al. 2010; Latimer, et al. 2019a; Ovens, et al. 2019]. The evaluation and treatment for refractory PID are not limited to the management discussed here.</p> <p>b. Pretreatment with doxycycline may reduce bacterial load, which may increase effectiveness of azithromycin or moxifloxacin [Durukan, et al. 2019].</p>	

**A 2-step treatment approach:** A 2-step approach to antimicrobial treatment has improved treatment success in published reports, leading to recommendations for 2-step treatment in Australian and UK treatment guidelines [ASHA 2018; Soni, et al. 2019]. The premise of the 2-step approach is that pretreatment with doxycycline has been shown to decrease the overall bacterial burden, making treatment with a second follow-up drug more efficacious [Bjornelius, et al. 2008; Anagrus, et al. 2013; Durukan, et al. 2019].

In Australia, cure rates have risen to >90% with the implementation of resistance-guided antimicrobial therapy (RGT) [Durukan, et al. 2019]. Individuals with an STI syndrome received 7 days of oral doxycycline 100 mg twice daily empirically and then, if found to have *M. genitalium* without macrolide resistance, received 2.5 g oral azithromycin over 4 days (1 g on day 1 and 500 mg daily on days 2 through 4). After initial treatment with doxycycline, individuals with macrolide-resistant *M. genitalium* received oral moxifloxacin 400 mg daily for 7 days. A test of cure was performed 2 to 4 weeks after treatment. The cure rate with the RGT approach was 92%, even in regions with reported quinolone resistance of 15% to 20% [Durukan, et al. 2019].

**Macrolide resistance:** Knowledge of the local prevalence of macrolide and quinolone resistance may help guide regimen choice, particularly when resistance testing is not readily available. Risk factors for macrolide-associated resistance

mutations include a recent STI, STI coinfection, and use of antibiotics within 30 days [Furegato, et al. 2019; Li, et al. 2020]. A substudy of the ANRS IPERGAY trial found a high prevalence of antibiotic-resistant *M. genitalium* in men who have sex with men (MSM) taking pre-exposure prophylaxis to prevent HIV infection [Bercot, et al. 2019]. Use of azithromycin as a standard treatment for gonorrhea and chlamydia has been associated with higher rates of macrolide resistance in MSM [Anagnrius, et al. 2013; Latimer, et al. 2019b].

In cases of treatment failure with macrolides and moxifloxacin, pristinamycin 1 g 4 times daily for 10 days has been effective in European and Australian studies [Bissessor, et al. 2015; Read, et al. 2018], but this treatment is not currently available in the United States.

**STI coinfections:** When coinfection with another sexually transmitted organism is present, it remains unclear based on available evidence whether *M. genitalium* is a true pathogen.

**Test of cure:** Test of cure can be considered after completion of treatment in patients who remain symptomatic. The timeframe used for test of cure in the published literature is highly variable. Existing guidelines from Europe, Australia, and the United Kingdom have recommendations ranging from  $\geq 2$  to  $\geq 5$  weeks after treatment [Jensen, et al. 2016; ASHA 2018; Soni, et al. 2019]. Testing too soon carries the risk of detecting residual noninfectious particles after treatment.

**Evaluation and treatment of sex partners:** Sex partners of individuals with symptomatic *M. genitalium* infection should be evaluated. There is insufficient evidence to clarify whether partners should receive treatment without testing or be treated only if infection is detected through a laboratory test. [Jensen, et al. 2016; Expert Working Group 2017; ASHA 2018; Soni, et al. 2019]. Now that diagnostic tests for *M. genitalium* are approved by the U.S. Food and Drug Administration, this Committee considers it reasonable to limit treatment to ongoing sex partners with positive test results.

## Special Populations

**Pregnant patients:** Moxifloxacin and doxycycline are generally *not recommended* for pregnant individuals. An azithromycin-only course of treatment could be considered. Given high rates of azithromycin resistance, a shared decision-making approach is warranted, balancing the risks of untreated *Mycoplasma genitalium* infection during pregnancy with possible adverse drug events associated with antibiotics not generally used during pregnancy.

At present, there is insufficient evidence regarding pregnancy complications and treatment benefits to recommend for or against screening in asymptomatic pregnant individuals [Wiesenfeld and Manhart 2017]; however, a meta-analysis of available studies has suggested significant associations with preterm birth and spontaneous abortion [Lis, et al. 2015]. In this same analysis, the risk of infertility was described as elevated but was not statistically significant [Lis, et al. 2015].

**Individuals with HIV:** Data are limited on *M. genitalium* infection in individuals with HIV. Although *M. genitalium* infection has been associated with viral shedding of HIV from the cervix in smaller studies of women with HIV in Kenya and Zimbabwe [Manhart, et al. 2008; Napierala Mavedzenge, et al. 2015], evidence for enhanced transmission with coinfection is lacking.

**Transgender individuals:** Data are lacking on *M. genitalium* infection in transgender individuals. As noted above, the specimen and site of optimal sensitivity for testing in transgender individuals have not been evaluated. There is insufficient evidence to support a recommendation for testing or treatment in asymptomatic transgender individuals.

## All Recommendations

### All RECOMMENDATIONS: Guidance on Screening, Diagnosis, and Treatment of *Mycoplasma genitalium*

#### Laboratory Testing

- Clinicians should not routinely screen for *Mycoplasma genitalium* in asymptomatic individuals. (A3)
- When testing is indicated, clinicians should use nucleic acid amplification testing (NAAT) to diagnose *M. genitalium*, with resistance testing if available. (A3)

#### Treatment

- Clinicians should prescribe treatment with oral moxifloxacin 400 mg daily for 7 to 14 days for individuals with confirmed cases of symptomatic *Mycoplasma genitalium* infection. (B2)
- Clinicians should consider using doxycycline for empiric treatment of persistent or recurrent urethritis or cervicitis while awaiting *M. genitalium* test results, to facilitate lead-in to a 2-step treatment approach. (B2)

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