

Vaginitis Reviewer Guide

Desktop Instructions

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Introduction

This policy establishes medical necessity and appropriateness criteria for molecular (nucleic acid amplification test [NAAT]) testing in the evaluation of vaginitis/vaginosis.

Medical Necessity Review

1. Covered Indications (Medical Necessity Met)

- a. Molecular vaginitis testing is considered medically necessary when ****ALL**** of the following are met:
 1. The patient has ****signs or symptoms consistent with vaginitis/vaginosis**** (e.g., abnormal vaginal discharge, odor, pruritus, irritation, dysuria, dyspareunia), documented in the medical record.
 2. The specimen is a ****single vaginal swab****, self-collected or clinician-collected, consistent with the manufacturer's FDA-cleared instructions.
 3. Testing is ordered to identify the cause among the principal etiologies of vaginitis — ****bacterial vaginosis, vulvovaginal candidiasis, and trichomoniasis**** — which together account for approximately 90% of cases and frequently co-occur (IDSA/ASM, Clinical Infectious Diseases, 2024).
 4. For patients where ****in-office microscopy is unavailable, results are equivocal, or empiric therapy has failed****, NAAT is an appropriate diagnostic step (ACOG, Vaginitis in Nonpregnant Patients, 2020).
2. NAAT is the ****recommended method for diagnosis of trichomoniasis**** given its high sensitivity (95.3–100%) and specificity (95.2–100%) compared with microscopy (ACOG, 2020).

3. Non-Covered / Not Medically Necessary

- a. Molecular vaginitis testing is ****NOT**** covered in the following circumstances (IDSA/ASM, 2024):
 - ****Screening of asymptomatic patients**** — these panels are not validated or intended for screening.
 - **Test of cure**** or confirmation of treatment response.
 - **Prognostic**** use.
- Repeat panel testing for the same episode without a change in clinical status.
- Testing performed outside the manufacturer's FDA-cleared age range (e.g., BD Max and Xpert Xpress MVP cleared for ≥18 years; Aptima BV and CV/TV cleared for ≥14 years).

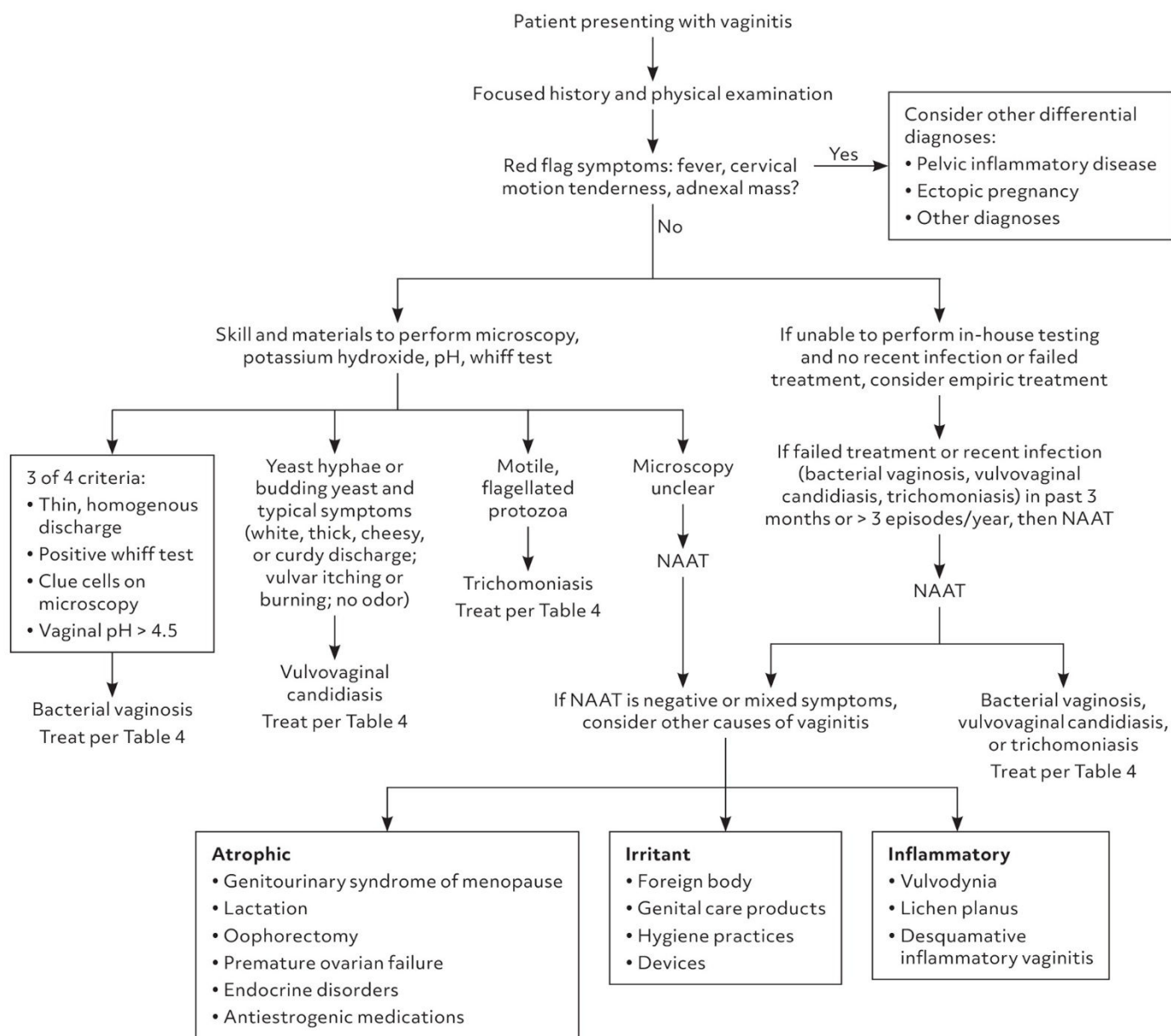
Single-organism assays targeting only *Gardnerella vaginalis* as a stand-alone diagnosis of BV, as no single sentinel organism reliably identifies BV (ACOG, 2020).

4. Clinical and Diagnostic Rationale

- a. Preferred first-line evaluation of symptomatic vaginitis remains a **complete history, examination, and clinic-based testing** (vaginal pH, KOH "whiff" test, saline and 10% KOH microscopy). For BV specifically, **Amsel criteria and Gram stain with Nugent scoring** remain the preferred and most cost-effective reference methods (ACOG, 2020).
- b. Multiplex NAAT panels demonstrate **higher sensitivity and negative predictive value than clinician assessment or point-of-care tests**, superior detection of mixed and co-infections, and — as a primary testing strategy — are associated with fewer repeat visits, more directed therapy, and lower overall cost (IDSA/ASM, 2024).
- c. FDA-cleared assay validation reported sensitivity/specificity of 95.0%/89.6% for BV, 91.7%/94.9% for the *Candida* species group, 84.7%/99.1% for *C. glabrata*, and 96.5%/95.1% for *T. vaginalis* (Schwebke et al., *Journal of Clinical Microbiology*, 2020).
- d. Independent PCR panel evaluation reported BV sensitivity/specificity of 93.1%/88.8%, *Candida* 96.0%/98.4%, with added detection of *T. vaginalis* missed by culture/microscopy (Amor et al., *PLoS One*, 2024).

5. Documentation Requirements

- a. The ordering record must include: presenting symptoms, relevant examination and/or point-of-care findings, the specific organisms/panel ordered, and rationale where in-office microscopy was not diagnostic. Co-testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* should be guided by STI risk assessment, given elevated STI co-infection rates in symptomatic vaginitis (IDSA/ASM, 2024).
- b. Review medical records, focused history and physical examination



NAAT = nucleic acid amplification test.

References

1. Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2024 Update by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM).
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3. Vaginitis in Nonpregnant Patients: ACOG Practice Bulletin, Number 215.
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6. Journal of Clinical Microbiology. 2020. Schwebke JR, Taylor SN, Ackerman R, et al.Observational
7. Evaluation of the Vaginal Panel Realtime PCR Kit (Vircell, SL) for Diagnosing Vaginitis: A Comparative Study With Routinely Used Diagnostics.
8. PloS One. 2024. Amor I, Alberola A, De Salazar A, et al.

Approvals	
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