

**Advisory Committee Briefing Material  
Urigen Pharmaceuticals, Inc.**

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Guideline Statement 3.

Cystoscopy and/or urodynamics should be considered when the diagnosis is in doubt; these tests are not necessary for making the diagnosis in uncomplicated presentations. *Expert Opinion*

The AUA treatment algorithm is shown in [Appendix 1](#), and AUA guideline is shown in [Appendix 2](#).

### **3.4 Role of Cystoscopy**

The preponderance of evidence shows that cystoscopy with hydrodistension is not a reliable diagnostic tool to positively establish IC/PBS; diagnosis based on symptoms and history is more reliable. There may be a role for cystoscopy to exclude other possible diagnoses in patients whose history and symptoms are inconclusive, and in those cases cystoscopy under local anesthesia may suffice. Despite the lack of supportive evidence, some still consider cystoscopy with hydrodistension an important diagnostic test for IC/PBS [Hand 1949, Messing 1978 and Gillenwater 1987]. The purported positive findings believed to be diagnostic for IC/PBS during the procedure are: Hunner lesions, glomerulations and/or or reduced anesthetic capacity.

Hunner lesions are rare and reported in 5-11% of patients ultimately diagnosed with interstitial cystitis [Nigro 1997, Ottem 2005 and Parsons 1990]. Hunner lesions cannot be readily diagnosed on awake (local anesthesia) cystoscopy [Doiron 2016]. The requirement for anesthesia and hydrodistension arises as there can be misdiagnoses of Hunner lesion as other lesions, such as biopsy scar [Parsons, 1996]. The absence of a Hunner lesion does not preclude the diagnosis of IC/PBS. They are more common in older patients than the typical younger patient [Doiron 2016, Jonat 2011]. Thus, the index IC/PBS patient does not have a Hunner lesion.

Glomerulations are more commonly seen but their presence or absence is also variable [Wennevik 2016]. They are present in approximately 60-80% of patients in most modern series with their presence being reported in as few as 30% of patients [Lokeshwar 2006, Denson 2000 and Standfor 2006]. Again, misinterpretation of glomerulations is also possible as they may have arisen from cystoscope trauma, or the trauma of hydrodistension [Parsons, 1996]. They have been reported to be equally present in both IC patients and asymptomatic controls [Waxman 1998]. There is poor correlation between glomerulation severity and symptoms [Ottem 2005, Doiron 2016 and Wennevik 2016]. Approximately 40-50% of patients have either no glomerulations or scant glomerulations [Ottem 2005 and Denson 2000]. Severe glomerulations (> 5 glomerulations per cystoscopy field and diffusely present across fields with the scope held 1 cm from the epithelium) are generally seen in Hunner lesion cases [Ottem 2005, Doiron 2016]. Interrater reliability is poor [Denson 2000]. Glomerulations may evolve over time [Hand 1949, Shear 2006]. Glomerulation grade does not correlate with improvement to