815X3: Infectious disease, bacterial vaginosis and vaginitis, quantitative real-time amplification of DNA markers for *Gardnerella vaginalis*, *Atopobium vaginae*, *Megasphaera* Type 1, Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), and *Lactobacillus* species (*L. crispatus* and *L. jensenii*), utilizing vaginal fluid specimens, algorithm reported as a positive or negative for high likelihood of bacterial vaginosis, includes separate detection of *Trichomonas vaginalis* and/or *Candida* species (*C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis*), *Candida glabrata*, *Candida krusei*, when reported

Public Comment	**Rationale**
87506 ($262.99)	• The procedure described by CPT 87506 (*Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal (GI) pathogen, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 6-11 targets*) **requires similar instrumentation, technology, and resource utilization** as the BD MAX™ Vaginal Panel (the BD MAX Vaginal Panel is performed on the same PCR platform as our suite of GI panels – the BD MAX System). • In amplified probe analysis, the number of optical channels is proportional to the magnitude of multiplexing and ability to speciate multiple targets of interest (e.g. 87506 describes the identification of pathogenic targets assessed in 6-11 unique optical channels.) The BD MAX Vaginal Panel requires **10 optical channels (see Table 1)** to produce a combination of results for bacterial, fungal, and parasitic infectious agents to determine the underlying cause of a patient's vaginitis. Therefore of the GI panel codes, **87506 (6-11 targets)** is the most accurate comparator. • Finally, 87506 is the most accurate crosswalk for the BD MAX Vaginal Panel given the **evaluation of different types of infectious pathogens within a singular procedure**. Specifically multiplex GI panels evaluate a combination of bacterial, viral, and parasite targets and the BD MAX Vaginal Panel evaluates bacterial, fungal, and parasite targets from a single patient specimen.

Table 1: BD MAX Vaginal Panel Targets & Optical Channels

Optical Channel	**Target Organism**
1	*Atopobium vaginae*
2	BVAB-2 & *Megasphaera-1*
3	*Gardnerella vaginalis*
4	*Lactobacillus* (*jensenii & crispatus*)
5	Internal Control
6	*Candida* group (*albicans, parapsilosis, tropicalis, dubliniensis*)
7	*Candida glabrata*
8	*Candida krusei*
9	*Trichomonas vaginalis*
10	Internal Control