Health Program & Insurance Guide for the BIOFIRE® Joint Infection (JI) Panel

bioMérieux developed the following health program & insurance guide for laboratories that administer the BIOFIRE® Joint Infection (JI) Panel, which is FDA-cleared for the simultaneous qualitative detection and identification of multiple bacterial and yeast nucleic acids and potentially associated markers of antimicrobial resistance from synovial fluid obtained from individuals suspected to have a joint infection such as septic arthritis and prosthetic joint infections in the United States. We describe below our current understanding of the coverage, coding and payment for administering the BIOFIRE JI Panel as of: January 1, 2023.

The information contained in this guide is not legal or coding advice; it is general information for reference purposes only. It is not intended to suggest any manner in which healthcare providers can increase or maximize compensation from any payer. It is not intended to guarantee coverage, coding or payment. This information is gathered from third-party sources and is subject to change without notice, including as a result of changes in laws, regulations, rules and policies. This information may not be all-inclusive and changes may have occurred subsequent to publication of this document. Before filing claims, healthcare providers should always check applicable laws and regulations, and consult individual payers regarding billing and compensation matters, including for specific coverage, coding and payment information. Healthcare providers are solely responsible for determining appropriate charging and billing practices, and for ensuring compliance with Medicare, Medicaid and all other third-party payer requirements, as well as accurate coding, documentation and medical necessity for the services provided. bioMérieux specifically disclaims liability or responsibility for the results or consequences of any actions taken in reliance on information in this general reference document.

About the BIOFIRE FILMARRAY Joint Infection Panel

The BIOFIRE® Joint Infection (JI) Panel is a multiplexed nucleic-acid-based, *in vitro* diagnostic test intended for use with the BIOFIRE® FILMARRAY® 2.0 or BIOFIRE® FILMARRAY® TORCH systems for the simultaneous detection and identification of multiple bacterial and yeast nucleic acids select antimicrobial resistance genes from synovial fluid obtained from individuals suspected to have a joint infection.

The following organisms are identified using the BIOFIRE JI Panel:

Gram Positive Bacteria

- *Anaerococcus prevotii/vaginalis*
- *Clostridium perfringens*
- *Cutibacterium avidum/granulosum*
- *Enterococcus faecalis*
- *Enterococcus faecium*
- *Finegoldia magna*
- *Parvimonas micra*
- *Peptoniphilus*
- *Peptostreptococcus anaerobius*
- *Staphylococcus aureus*
- *Staphylococcus lugdunensis*
- *Streptococcus* spp.
  - *Streptococcus agalactiae*
  - *Streptococcus pneumoniae*
  - *Streptococcus pyogenes*

Gram Negative Bacteria

- *Bacteroides fragilis*
- *Citrobacter*
- *Enterobacter cloacae complex*
- *Escherichia coli*
- *Haemophilus influenzae*
- *Kingella kingae*
- *Klebsiella aerogenes*
- *Klebsiella pneumoniae* group
- *Morganella morganii*
- *Neisseria gonorrhoeae*
- *Proteus* spp.
- *Pseudomonas aeruginosa*
- *Salmonella* spp.
- *Serratia marcescens*

Antimicrobial Resistance Genes

- CTX-M
- KPC
- NDM
- ***van***A/B
- IMP
- *mecA/C* and MREJ (MRSA)
- OXA-48-like
- VIM

Yeast

- *Candida*
  - *Candida albicans*

The BIOFIRE JI Panel is intended for use by trained medical and laboratory professionals in a laboratory setting or under the supervision of a trained laboratory professional.

The BIOFIRE JI Panel is indicated as an aid in the diagnosis of specific agents of joint infections and results should be used in conjunction with other clinical and laboratory findings. Negative results may be due to infection with pathogens that are not detected by this test, pathogens present below the limit of detection of the assay, or infection that may not be detected in a synovial fluid specimen. Positive results do not rule out co-infection with organisms. The BIOFIRE JI Panel is not intended to monitor treatment for joint infection.

For more information on the BIOFIRE JI Panel, please consult the Instructions for Use located at: https://www.biofiredx.com/support/documents/.

Health Program & Insurance Guide for the BIOFIRE® Joint Infection (JI) Panel

Coverage

Coverage is a payer's determination that items and services are medically necessary for a patient and may be included under the patient's health insurance benefits. Coverage varies by payer. Healthcare providers should consult with individual payers regarding their coverage policies, including any applicable coverage criteria or documentation requirements.

For more information on Medicare and select state Medicaid programs coverage of the BIOFIRE® JI Panel, please consult CodeMap *http://www.codemap.com/biofiredx*.

Coding

Coding enables healthcare providers to communicate to payers the items and services furnished to a patient in order to obtain payment for those items and services. It is the sole responsibility of the healthcare provider to determine the most appropriate codes to report on a claim, upon consultation of specific payer policies.

Based on currently available information, the BIOFIRE JI Panel may be described by the following CPT code:

CPT code 87999 *– Unlisted microbiology procedure.*
DEX Z-Code™ : Z01WQ* *– Joint Infection (JI) Panel*
**Tests using CPT® code 87999 will also require a Z-code, pursuant to MolDX.*

Payment

Payment is the amount that a payer renders to a healthcare provider for furnishing items and services to a patient. Patients may also have cost-sharing obligations, including deductibles, coinsurance or copayments, depending on their health insurance benefits. Payment amounts vary by payer and by geographic location, and are frequently updated, but are generally an allowable amount minus any patient cost-sharing amount. Healthcare providers should consult with individual payers regarding applicable current allowable amounts.

For more information on Medicare and select state Medicaid programs' allowable rates for the BIOFIRE JI Panel, please consult CodeMap *http://www.codemap.com/biofiredx*. Medicare rate limits can also be found on the CMS website within the Clinical Laboratory Fee Schedule (CLFS) section; the CLFS is updated quarterly.

It is recommended that healthcare providers consult with individual payers regarding allowable amounts for the BIOFIRE JI Panel. Allowable information can be found in your participating provider agreements with your payers or you can access your payers' online provider resources. For customers that are employees or part of health systems and or Hospitals, please contact your Revenue Cycles Management or Managed Care departments.

Additional Information

In providing this health program & insurance guide, bioMérieux makes no warranties, express, implied or statutory, including, but not limited to, warranties of merchantability, fitness for a particular purpose and/or non-infringement. bioMérieux assumes no responsibility for omissions or errors contained in this guide. This guide presents no promise, commitment, statement or guarantee by bioMérieux concerning proper billing or coding practices or levels of payment or charges. This information does not constitute reimbursement or legal advice. The existence of codes does not guarantee coverage or payment for any procedure by any payer. The healthcare provider is solely responsible for determining the appropriate coverage, coding and payment policies for individual patients.

To ensure compliance with Federal and State laws and regulations, including HIPAA, bioMérieux is unable to provide specific billing guidance, and/or support with patient appeals.

bioMérieux does not recommend codes for specific cases. bioMérieux does not promote the off-label use of its diagnostic tests.

For more information regarding bioMérieux or the BIOFIRE JI Panel, please visit our website: www.biomerieux-diagnostics.com.