Health Program & Insurance Guide for the BIOFIRE® FILMARRAY®

Meningitis/Encephalitis (ME) Panel

bioMérieux developed the following health program & insurance guide for laboratories that administer the BIOFIRE® FILMARRAY® Meningitis/Encephalitis (ME) Panel, which is FDA-cleared for the simultaneous qualitative detection and identification of nucleic acids from multiple bacteria, viruses, and yeast directly from cerebrospinal fluid (CSF) specimens obtained via lumbar puncture from individuals with signs and/or symptoms of meningitis and/or encephalitis, in the United States. We describe below our current understanding of the coverage, coding and payment for administering the BIOFIRE ME Panel as of: September 1, 2022.

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 Meningitis/Encephalitis Panel

The BIOFIRE ME Panel, for use with the BIOFIRE® FILMARRAY® systems, is a qualitative multiplexed nucleic acid-based *in vitro* diagnostic test capable of the simultaneous detection and identification of nucleic acids from multiple bacteria, viruses, and yeast directly from cerebrospinal fluid (CSF) specimens obtained via lumbar puncture from individuals with signs and/or symptoms of meningitis and/or encephalitis..

The BIOFIRE ME Panel is intended for the detection and identification of the following organism types and subtypes:

Bacteria	Viruses
• *Escherichia coli* K1 • *Haemophilus influenzae* • *Listeria monocytogenes* • *Neisseria meningitidis* • *Streptococcus agalactiae* • *Streptococcus pneumoniae*	• Cytomegalovirus (CMV) • Enterovirus (EV) • Herpes simplex virus 1 (HSV-1) • Herpes simplex virus 2 (HSV-2) • Human herpesvirus 6 (HHV-6) • Human parechovirus (HPeV) • Varicella zoster virus (VZV)
Yeast	
• *Cryptococcus (C. neoformans/C. gattii)*	

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

The BioFire ME Panel is indicated as an aid in the diagnosis of specific agents of meningitis and/or encephalitis and results are meant to be used in conjunction with other clinical, epidemiological, and laboratory data. Results from the BioFire ME Panel are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not rule out co-infection with organisms not included in the BioFire ME Panel. The agent detected may not be the definite cause of the disease. Negative results do not preclude central nervous system (CNS) infection. Not all agents of CNS infection are detected by this test and sensitivity in clinical use may differ from that described in the package insert.

The BioFire ME Panel is not intended for testing of specimens collected from indwelling CNS medical devices.

The BioFire ME Panel is intended to be used in conjunction with standard of care culture for organism recovery, serotyping, and antimicrobial susceptibility testing.

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

Health Program & Insurance Guide for the BIOFIRE® FILMARRAY®

Meningitis/Encephalitis (ME) 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® ME 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 ME Panel may be described by the following CPT code:

> ***CPT code 87483*** *– Infectious agent detection by nucleic acid (DNA or RNA); central nervous system pathogen (eg, Neisseria meningitidis, Streptococcus pneumoniae, Listeria, Haemophilus influenzae, E. coli, Streptococcus agalactiae, enterovirus, human parechovirus, herpes simplex virus type 1 and 2, human herpesvirus 6, cytomegalovirus, varicella zoster virus, Cryptococcus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets*

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 ME 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 ME 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.

Applicable FARS/DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT®, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

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 ME Panel, please visit our website: www.biomerieux-diagnostics.com.

BFR0002-1489-01