BRONSON Laboratory

Notification Date: February 6, 2020

RE: Laboratory Compliance - Annual Provider Notification Letter

Bronson Healthcare System maintains an active compliance program that reflects our commitment to conduct business in compliance with all federal, state and local laws. As a participant in federally funded healthcare programs, Bronson Lab delivers annual provider information and education regarding laboratory compliance, billing and coding guidelines, and to inform our provider clients on the responsibilities we share together. This letter serves as the annual notice to provide helpful information regarding compliant ordering and processing of clinical laboratory tests for our shared patient per Medicare/Medicaid program requirements and Bronson Compliance policies.

Medical Necessity

As the physician, you are responsible for documenting medical necessity in the patient's medical record, including physician signature, and for providing appropriate diagnostic information in the form of ICD-10 codes to the highest level of specificity or a narrative to Bronson. The Office of Inspector General (OIG) takes the position that a physician who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act. Please follow long-standing federal and Bronson policy that patients' medical records must include a valid laboratory order or your signed documentation of medical necessity for ordering tests.

Medicare will only pay for tests that meet the Medicare coverage criteria and are medically necessary for the diagnosis or treatment of the individual patient. Tests used for routine screening of patients without regard to their individual need are not usually covered by the Medicare Program, and therefore are not reimbursed.

Valid Lab Orders - Test Order Requisition

To ensure accurate processing and testing, efficient patient identification and timely reporting of laboratory results, **valid laboratory orders** include the following:

- Patient's full legal name, date of birth, ICD-10 or diagnostic narrative for tests ordered, collection date and time, source (when applicable), and the licensed ordering practitioner's name and signature.
- Although the provider signature is not currently required on laboratory requisitions, when signed, the requisition will serve as acceptable documentation of a physician order for the testing.
- In the absence of a signed requisition, documentation of your intent to order each laboratory test must be included in the patient's medical record and available to Bronson upon request. (Signature stamps are NOT acceptable).
- Custom Profiles may be used if patient specific medical necessity is recorded in the patient's medical records and clearly marked on the Test Order Requisition.
- Documentation must accurately describe the individual tests ordered; it is not sufficient to state 'labs ordered'.

The pre-printed test order requisition is the tool used to communicate your valid order to the laboratory, but is NOT considered the 'valid order' as defined by Medicare. Upon request by Bronson or its payers/auditors, ordering providers are required to provide any/all chart documentation, including physician signature that reflects the actual lab order and supports the authenticity and medical necessity of the lab order(s) submitted.

- A standard Bronson test requisition used when ordering tests is designed to ensure you provide all Federally mandated 'valid order' elements and are ordering only those tests which you assessed as appropriate and medically necessary for the treatment and diagnosis of our mutually shared patient**. Please complete the test order requisition each time with the required information as detailed above.**
- If Bronson receives an incomplete Bronson or non-Bronson order requisition form, the processing of your test order may be delayed. As necessary to meeting mandated valid order data requirements, Bronson will contact physicians to clarify or provide those elements missing.

Custom Profiles

As provided in this letter, Bronson Laboratory offers a set of non-standard diagnostic panels approved by our Medical Staff. Medicare regulations and the OIG require that we notify you annually to these tests and their

appropriate use. These are a specific group of commonly ordered tests not defined by the American Medical Association (AMA) or Centers for Medicare and Medicaid services. Some panels cascade when initial test results are positive or outside normal parameters and reflex to a second related test or further testing as medically appropriate. These panels may be ordered as a whole, rather than ordering each test individually when each test is medically necessary. Mandated testing criteria set by government, accrediting agencies, evidence-guided practices in laboratory medicine and avoidance of performing unnecessary testing help dictate which tests are subject to reflexive testing. Bronson Laboratory will perform reflex testing upon result of an initial laboratory test as outlined in the Test Catalog online at http://bronsonlab.testcatalog.org/. To the extent that you order one of these non-standard panels, the OIG has asked us to advise you of the following:

- The Medicare program provides separate reimbursement to the laboratory for each individual component contained in the non-standard panel;
- Ordering non-standard panels may result in the ordering of tests which are not covered, reasonable or necessary and that tests will not be billed to Medicare except for the purpose of receiving a denial.
- Current Procedural Terminology (CPT) Codes and information on available services are also provided in the Bronson Laboratory Test Catalog as a convenience to our clients
- The OIG takes the position that an individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal and administrative law. The laboratory will not knowingly bill Medicare for tests that are not covered, reasonable, or necessary.

The Model Compliance Plan also suggests that we provide you with a copy of the Medicare laboratory fee schedule and advise you that the Medicaid reimbursement amount may be equal to or less than the amount of Medicare reimbursement. This information is being provided to advise you of the federal program reimbursement the hospital will receive on the tests you order. The Medicare Laboratory Fee schedule is available at http://www.cms.hhs.gov/ClinicalLabFeeSched. Medicaid reimbursement will be equal to or less than Medicare reimbursement. Further Local Coverage Determinations (LCD) information is available at https://www.wpsgha.com/wps/portal/mac/site/policies/guides-and-resources/lcds-and-coverage-articles

We greatly appreciate your support for our Laboratory Compliance Program. If you have any questions or comments regarding the hospital's Laboratory Compliance Program, please do not hesitate to contact one of us at the numbers listed below.

Sincerely,

Lois VanEnk, MBA MT(ASCP)SC
Bronson Laboratory System Director
269 341-7670
vanenkl@bronsonhg.org

Christine Sangalli
VP Chief Compliance Officer
Bronson Healthcare Group
269 341-6065
sangallc@bronsonhg.org

AMA Approved Panels	Tests Included in Panel
Acute Hepatitis Panel	Hepatitis B surface antigen, Hepatitis B core antibody IgM, Hepatitis A antibody IgM, Hepatitis C Antibody
Basic Metabolic Panel/Calcium	Sodium, Potassium, Chloride, Carbon Dioxide, Creatinine, Urea Nitrogen (BUN), Glucose, Calcium
Basic Metabolic Panel/Ionized Ca	Sodium, Potassium, Chloride, Carbon Dioxide, Creatinine, Urea Nitrogen (BUN), Glucose, Ionized Ca
Comprehensive Metabolic Panel	Sodium, Potassium, Chloride, Carbon Dioxide, Creatinine, Urea Nitrogen (BUN), Glucose, Calcium (Total), Total Protein, Albumin, AST, ALT, Alkaline Phosphatase, Total Bilirubin
Electrolyte Panel	Sodium, Potassium, Chloride, Carbon Dioxide
Hepatic Function Panel	Albumin, Alkaline Phosphatase, ALT, AST, Total Bilirubin, Direct Bilirubin, Total Protein
Lipid Panel	Cholesterol, HDL Cholesterol, Triglycerides, Calculated LDL Cholesterol, Non HDL Cholesterol
Renal Panel	Sodium, Potassium, Chloride, Carbon Dioxide, Creatinine, Urea Nitrogen (BUN), Glucose, Calcium (Total), Albumin, Phosphorus
Additional Panels Offered at Bronson Laboratory	
Acid Fast Bacilli (AFB) Cultures	Acid Fast Bacilli cultures on sputum will contain PCR for Mycobacterium tuberculosis complex and the Rifampin gene resistance.
Allergen Panels	*See full descriptions in the Bronson Laboratory Users Guide.* **Childhood Panel:** Alternaria, Cat, Cladosporium, Dust Mite(DF), Dust Mite(DP), Dog, Roach, Cod, Egg*, Milk*, Mouse Urine, Peanut*, Soy,Shrimp, Walnut, Wheat and Total IGE. **Food Panel**: Almond, Cashew, Codfish,Hazelnut, Milk*, Egg White*, Peanut*, Salmon, Soybean, Tuna, Wheat, Walnut, Scallop, Shrimp, Sesame seed, Total IgE **Respiratory Panel** : Alternaria, Cat, Dust mite(DF & DP), Dog, Roach, Aspergillus, Bermuda Grass, Red Cedar, Cladosporium, Cottonwood, Timothy Grass, Mouse Urine, Mulberry, Nettle, Penicillium, Russian Thistle, Birch, Elm, Maple, Marsh Elder, Ragweed, Oak, Total IGE. **Venom Panel**: Venom from honey bee, paper wasp, white faced hornet, yellow hornet, yellow jacket *If the whole allergen for Peanut, Milk or Egg are positive, the corresponding allergen component profile is reflexively ordered
Anaerobe Culture	Aerobic Culture ordered in conjunction with Anaerobe Culture
Blood Culture Identification Panel	Positive blood cultures reflex to PCR panel to detect Enterococcus, Listeria monocytogenes, Staphylococcus species, Staph aureus, Streptococcus species, Strep agalactiae, Strep pneumonia, Strep pyogenes, Acintetobacter baumannii, Enterobacteriaceae family, Enterobactor cloacae complex, Escherichia coli, Klebsiella pneumonia, Proteus species, Serratia marcescens, Haemophilus influenza, Neisseria meningitides, Pseudomonas aeruginosa, Candida albicans, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis and the three resistance genes, KPC (carbapenemase), mecA(methicillin), and vanA /B (vancomycin).
Bilirubin Panel	Total Bilirubin, Direct Bilirubin, Calculated Indirect Bilirubin
Cardiolipin Antibodies	AntiCardiolipin IgG & IgM
CBC	CBC without and with differential are panels offered. Orders for combinations of individual CBC component tests which include a differential will be converted to CBC with differential to ensure adequate specimen quality assessment per policy.
Celiac Disease Cascade	Anti-gliadin (deamidated) IgA antibody & Anti-tissue transglutaminase IgA antibody*****. Reflex tests can include: tissue transglutaminase IgG and gliadin (deamidated) IgG.
Coagulation Genetic Testing	Factor II (G20210A) and Factor V Leiden (G1691A) mutations
Connective Tissue Disease Cascade	Anti-nuclear antibody (ANA) and Anti-cyclic citrullinated peptide (CCP)* Reflex tests can include: Anti-DNA Double Strand and ENA reflex panel- Ro(SSA), LA(SSB), Chromatin, Riboprotein, SCL70, Centromere, JO-1, RNP70, and Smith RNP, RNP and Smith.
CSF Evaluation	Cell count and differential, protein, glucose and microbiology culture including Meningitis/Encephalitis Panel by PCR.
DIC Screen	D-Dimer, fibrinogen, partial thromboplastin time, platelet count, prothrombin time, and peripheral blood review for the presence of schistocytes
Epstein Barr Antibody Panel	EBV Early Antigen EA, Heterophile Ab, Nuclear Antigen NA IgG, Viral Capsid VCA IgG & IgM
Gastrointestinal PCR Panel	Campylobacter (C.jejuni/C.coli/C.upsaliensis), Clostridium difficile (C. difficile) toxin A/B, Plesiomonas shigelloides, Salmonella, Vibrio (V. parahaemolyticus/V. vulnificus/V. cholera), including specific identification of Vibrio cholera, Yersinia enterocolitica, Enteropathogenic Escherichia coli (EPEC), Enteroaggregative Escherichia coli (EAEC), Enterotoxigenic Escherichia coli (ETAC) lt/st, Shiga-like toxin-producing Escherichia coli (STEC) stx1/stx2 (including specific identification of the E.coli O157 serogroup within STEC), Cryptosporidium, Cyclospora cayetensis, Entamoeba histolytica, Giardia lamblia, Adenovirus F 40/41, Astrovirus, Norovirus GI/GII, Rotavirus A, Sapovirus (Genogroups I,II,IV, and V)

Bronson Panels	Tests in Panel
Group B Strep PCR	Positive specimens on Penicillin allergic patients reflex to a Susceptibility.
Hemoglobin Electrophoresis Scr	Electrophoresis repeated with acid pH when abnormal hemoglobins are detected
Herpes Simplex IgG Antibodies	Herpes Simplex Type 1 and Type 2 IgG Antibodies
Herpes Simplex & Varicella zoster PCR	Herpes Simplex Type 1, Type 2 & Varicella zoster PCR
Influenza Panel	Influenza A, Influenza B and RSV
Meconium Toxicology; Screen and Reflex Confirmation	Amphetamines, Methamphetamines, THC, Cocaine, Opiates Methadone, Oxycodone, Buprenorphine, Tramadol - See full description in the Bronson Laboratory Users Guide.
Meningitis/Encephalitis Panel	Screens for Escherichia coli K1, Haemophilus influenza, Listeria monocytogenes, Neisseria meningitides, Streptococcus agalactiae, Streptococcus pneumonia, Cytomegalovirus (CMV), Enterovirus, Herpes simplex 1 & 2 (HSV-1 & 2), Human herpesvirus 6 (HHV-6), Human parechovirus, Varicella zoster virus (VZV), and Cryptococcus neoformans/gattii.
Microbiology Cultures	The following culture orders will always include Gram Stain/Smear: Acid Fast Bacilli (AFB), Respiratory, Quantitative, & Bacterial (abscess fluid, sterile body fluid and all surgical specimens). Reflex Identification testing and Susceptibilities as appropriate.
Monoclonal Protein Evaluation	Serum protein electrophoresis, Serum kappa and lambda free light chains, Serum Immunofixation performed if indicated by pathologist review.
Obstetric Panel	ABO & Rh Blood Typing, Antibody Screen*, Syphilis IgG antibody, Rubella antibody, Complete Blood Count (CBC) w/diff, Hepatitis B surface antigen, HIV screen. Reflex Syphilis testing confirmation as appropriate.
Ova and Parasite Complete Screen	Ova and parasites (direct and concentrated exam), Ova & Parasite Screen Giardia, Ova Parasite Cryptosporidium, Trichrome Stain
PAP reflex to HPV	ThinPrep Pap smears of patients ≥21 years of age with a diagnosis of atypical squamous cells of undetermined significance (ASCUS) will be reflexively forwarded for Human Papillomavirus (HPV) DNA High Risk with 16/18 genotyping per Bronson Cytology reflex HPV policy.
Protein Electrophoresis, Serum or Urine	Immunofixation performed if indicated by pathologist review.
Respiratory Infectious Agent Panel	See full descriptions in the Bronson Laboratory Users Guide. Screens for Flu A, Flu B, RSV, Parainflunenza, Adenovirus, Rhinovirus, Metapneumovirus, Enterovirus, Coronavirus, Pertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae.
STD Panels	Chlamydia trachomatis by PCR, Gonococcus by PCR Chlamydia trachomatis by PCR, Gonococcus by PCR, Trichomonas Vaginalis by PCR
Sweat Chloride	Two arm reporting: Testing will be done on each arm and each order will consist of 2 times the analysis and 2 times the collection.
Syphilis Testing	Treponemal antibody (Syphilis, Total Antibody): Positive and equivocal results reflex to RPR. RPR: Non-reactive specimens are forwarded to MDCH for further testing.
Thrombophilia Cascade	Anti-thrombin III activity, protein C activity, protein S antigen, prothrombin time, factor VIII activity, partial thromboplastin time, DRVVT, mixing studies*
Thyroid Function Cascade	If TSH is <0.27 mIU/mL, then free T4 is performed. If free T4 is <2.0 ng/mL and TSH is <0.1 mIU/mL, then total T3 is performed. If TSH is >4.2 mIU/mL, then free T4 and anti-thyroid peroxidase are performed.
Type and Screen	ABO / Rh Blood Type and Antibody Screen*
Urine Culture If	Urinalysis with reflex to culture if indicated by selected criteria
Urine Drug of Abuse Screen	Amphetamine, barbiturate, benzodiazepine, cocaine, opiates, THC
Urine Drug Screen 8	Amphetamine, barbiturate, benzodiazepine, cocaine, opiates, THC ,oxycodone & fentanyl
Urine Opioid Drug Screen	Opiate, buprenorphine, methadone, oxycodone, fentanyl

Reference lab testing is also covered by Medicare regulations with regard to medical necessity. Bronson utilizes Mayo Clinic Laboratories. The information above is contained in the Bronson Laboratory Users Guide available in print and on the Bronson Intranet at http://bronsonlab.testcatalog.org

***Additional tests may be performed based on initial test results. See testing algorithm in the Bronson Laboratory Users Guide.**