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December 30, 2019

To our Valued Partners:

BLA Partners, LLC d/b/a Aspenti Health™ & BLA of Massachusetts, LLC d/b/a Aspenti Health™ (collectively, "Aspenti") maintain 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, Aspenti provides this annual notice to providers to educate providers regarding laboratory compliance, billing and coding guidelines, and to inform our provider clients on the responsibilities we share.

This annual notice specifies current Medicare/Medicaid program requirements and Aspenti policies. Please carefully review the information.

Aspenti must rely on you, our provider clients, for the following key compliance elements:

## MEDICAL NECESSITY

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. State Medicaid agencies and many commercial payors have the same restrictions. Criteria to establish medical necessity for drug testing must be based on patient-specific elements identified during the clinical assessment and documented by the provider in the patient's medical record. 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. As a participating provider in the Medicare Program, Aspenti, has a responsibility to make a good faith effort to ensure all tests requested are performed and billed in a manner consistent with all federal and state law regulations.

As the ordering provider, you are responsible for documenting medical necessity in the patient's medical record (including physician/practitioner signature) and for providing appropriate diagnostic information in the form of ICD-10 codes to the highest level of specificity to Aspenti. *The Office of Inspector General (OIG) takes the position that a physician or practitioner who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act, or other civil, criminal, and administrative sanctions and remedies available under law.*

Guidance issued by the Centers for Medicare & Medicaid Services (CMS) in past years, as well as increased enforcement actions by government and commercial payors, including increased use of pre and post-payment audits, has encouraged Aspenti to proactively adopt policies requiring that physicians or practitioners provide signed, patient-specific orders to support testing. Aspenti also reminds physicians and practitioners that patients' medical records must include documentation of medical necessity for each of the tests ordered. In cases where testing patterns or data indicate a risk that services may not meet the criteria for medical necessity established by CMS, Aspenti may request additional information from providers. It is important for providers to be mindful that

applying the same testing profile to every patient, without reflection of their individual needs, may result in medically unnecessary testing.

## DISCLOSURE OF EXCLUSIONS FROM FEDERAL HEALTHCARE PROGRAMS

Under federal law, no payment will be made by any federal healthcare program for any items or services furnished, ordered, or prescribed by an excluded individual or entity. Under the CMS rules, providers must not employ or contract with individuals or entities excluded from participation in any health care program or debarred by the U.S. General Services Administration (GSA). CMS does not permit payments under the plan for services furnished by an individual or entity who is excluded from participation. CMS has further advised states that they should require providers to search the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG) website monthly to capture exclusions and reinstatements. Professionals who are required to be licensed shall notify Aspenti in writing within (5) days of receiving any written or oral notice of any adverse action, including, without limitation, exclusion from participation in any federal or state health care or procurement programs, any filed and served malpractice suit or arbitration action; any adverse action by a Licensing Board pending or taken; any adverse action resulting in the filing of a report with a Licensing Board; any revocation of DEA license; a conviction of any felony or any crime of moral turpitude; or any action against any certification under the Medicare or Medicaid programs.

List of Excluded Individuals/Entities (LEIE): The OIG established a program to exclude individuals and entities found to have violated federal law and/or regulations. The effect of an OIG exclusion from federal healthcare programs is that no federal healthcare program payment may be made for any items or services (1) furnished by an excluded individual or entity, or (2) directed or prescribed by an excluded physician or practitioner (42 CFR 1001.1901). This payment ban applies to all methods of federal program reimbursement, whether payment results from itemized claims, cost reports, fee schedules or a prospective payment system (PPS). Any items and services furnished by an excluded individual or entity are not reimbursable under federal health care programs. In addition, any items and services furnished at the medical direction or prescription of an excluded person are not reimbursable when the individual or entity furnishing the services either knows or should know of the exclusion. This prohibition applies even when the federal payment itself is made to another provider, practitioner or supplier that is not excluded.

System for Award Management (SAM) is the Official U.S. Government system that consolidated the capabilities of Central Contractor Registration/Federal Agency Registration, Online Representations and Certifications Application and the List of Parties Excluded from Federal Procurement and Non-procurement Programs (EPLS). The General Services Administration (GSA) maintains a single comprehensive list of individuals and firms excluded by Federal government agencies from receiving federal contracts or federally approved subcontracts and from certain types of federal financial and nonfinancial assistance and benefits. The EPLS was originally created for information and use by Federal agencies.

Medicaid State Sanction Data**:** Many states maintain their own database of individuals and entities they sanction. Several states call for or require health care entities to screen against this list. This is in addition to, not in lieu of, screening against the Federal sanction information.

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## TEST ORDER REQUISITION

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

Patient's full legal name, date of birth, reason (diagnosis) for each test ordered, clear indication of each test requested, date(s) of collection, specimen source (when applicable), and the licensed ordering practitioner's name, address, and NPI number. Requisitions must be signed and dated by the provider, to be valid orders. Unsigned requisitions may be used if an active signed patient-specific recurring order is on file with Aspenti, that clearly delineates the ordered frequency and duration of testing, medical necessity is recorded in the patient's medical records, and the intent to order testing in accordance with the recurring order is clearly marked on the Requisition. Signature stamps and/or photocopied signatures are NOT acceptable. Reference Medicare Learning Network (MLN) Fact Sheet on "Complying with Medicare Signature Requirements," ICN 905364 May 2018, for further details. Providers utilizing electronic signatures are responsible for complying with Medicare signature requirements as outlined in Medicare Program Integrity Manual, Chapter 3, Section 3.3.2.4 (Signature Requirements).

Although the provider signature is not legally required on laboratory requisitions, without such, a valid order for laboratory services only exists if documentation of intent to order each laboratory test for each collection date is included in the provider's signed notes with the patient's medical record, and such records are readily available to Aspenti upon request. Documentation must accurately describe the individual tests ordered; it is not sufficient to state 'labs ordered'. To decrease operations burden on providers and Aspenti staff to obtain necessary patient medical records, Aspenti requests providers submit orders ex. a signed requisition or a patient-specific recurring order to support all testing.

## TEST ORDERING

A standard Aspenti Requisition form, Aspenti Recurring Order form, Aspenti's electronic ordering software or providers' electronic ordering software should be used when ordering tests. These forms are designed to emphasize provider choice and encourage ordering only those tests which providers believe are appropriate and medically necessary for the treatment and diagnosis of each patient. If Aspenti receives a non-Aspenti form or an incomplete Aspenti order form, test processing may be delayed. As necessary, Aspenti will contact providers to resubmit the test order on an Aspenti requisition form or clarify specific testing ordered.

### *Custom Profiles and Recurring Orders*

Recent policy changes from Medicare Administrative Contractors support a growing movement away from providers' use of non-patient specific testing profiles when ordering laboratory testing. Aspenti supports these compliance efforts and has taken the necessary steps to better ensure that only medically necessary tests are ordered for each patient.

Aspenti does not accept "Standing Orders" or the default to a standing order. Aspenti will work with all providers to ensure that patient-specific orders support all testing delivered and billed by Aspenti. This may be accomplished by using a single instance signed Aspenti Requisition form or

Aspenti Recurring Order form. Aspenti also will accept valid orders through its electronic ordering software or through interfaces with providers' electronic medical records or ordering systems.

The provider has the choice to order to create one or more custom profiles to make ordering laboratory services more efficient. It is important to note that the use of custom profiles may result in the ordering of tests that are not medically necessary or are not covered. Aspenti encourages providers to use custom profiles only when assured that all tests in the profile are appropriate and medically necessary for the clinical needs of the patient on the date ordered. Providers using custom profiles will be required to meet with an Aspenti associate to review their utilization and their custom profiles no less than on an annual basis. Additionally, providers must sign an acknowledgement stating that they understand the implications and risks of using custom profiles.

Providers may use patient-specific recurring orders for patients where it is medically necessary to order regular laboratory testing over an extended course of treatment. Recurring Orders must contain the ordering provider's printed name and NPI Number, the patient's name and date of birth, the diagnosis that supports laboratory testing, the testing requested, the maximum frequency of testing, the duration of the recurring order, and the provider's signature and date. Recurring orders should only be used in connection with extended treatment by the same ordering provider, and when the patient has same diagnosis code(s) for all testing. Recurring orders shall not exceed 365 days from the original order date, or any lesser term defined by State or Federal law, regulation, or guidance.

Recurring orders are to be reviewed on a regular basis, to be no longer than once per year. Providers may amend a recurring order at any time or may order testing on a single date of collection that deviates from the recurring order by using a signed Requisition form. Aspenti suggests that providers keep a copy of the patient's recurring order readily available and in the patient's medical record when ordering laboratory test services as a reference to help ensure that only medically necessary tests are ordered.

### *Clinical Consultant*

Aspenti's clinical consultant is available to discuss providers' testing needs and any questions that providers may have about Aspenti's testing services. Aspenti's clinical consultant and Chief Medical Officer, Dr. Jill Warrington, can be reached at 1-866-ASPENTI (1-866-277-3684) or via clientservices@aspenti.com.

### *Verbal Test Orders*

Medicare regulations require that all orders for laboratory tests be in writing. If a provider or his/her authorized representative orders a test by telephone or wishes to add testing to an existing order, a written order is required to support the verbal order. In these cases, Aspenti will send a written confirmation of the verbal order request to the ordering provider for return. Testing will not be performed until a written confirmation or a properly completed Aspenti Requisition form is received.

### *Advance Beneficiary Notice*

If a 'non-covered' diagnosis is used for a Medicare patient, the patient must be notified prior to specimen collection and given the opportunity to sign the Advance Beneficiary Notice (ABN). The ABN must be completed for any Medicare patient where claim denial is suspected based on medical necessity or frequency limitations. The signed, original ABN must be attached to the original lab order prior to or with submission for testing. Per Medicare rules, routinely requesting the ABN on all Medicare beneficiaries is considered an unacceptable practice.

## MEDICARE NATIONAL AND LOCAL COVERAGE DETERMINATIONS

The Medicare Program publishes National Coverage Determination (NCDs) and local Medicare contractors publish Local Coverage Determinations (LCDs) for certain tests. These policies identify the conditions for which the included tests are or are not covered or reimbursed by Medicare with reference to specific diagnostic information. LCDs that apply to qualitative drug screens (presumptive tests), and confirmatory or quantitative drug tests (definitive testing) can be found through the Medicare website at https://www.cms.gov/medicare/coverage/determinationprocess/LCDs.

Aspenti will also provide these LCDs to providers upon request.

The LCD issued by National Government Services, Inc. (NGS) entitled "Urine Drug Testing (L36037)" provides guidance regarding appropriate indications and expected frequency for Urine Drug Testing (UDT). This policy is applicable to laboratories located in NGS's jurisdiction, which encompasses Vermont, and the same or similar requirements have been or may be adopted by the individual CMS contractors nationwide. Aspenti is working to ensure compliance with these standards by itself and providers who order testing from Aspenti. Aspenti adopted a Compliance Program that reflects the OIG Clinical Laboratory Compliance Program.

### *CMS National Coverage Policy*

Title XVIII of the Social Security Act, Section 1862(a) (1) (A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.
Code of Federal Regulations (CFR) Title 42, Part 410.32 indicates that diagnostic tests may only be ordered by the treating physician (or other treating practitioner acting within the scope of his/her license and Medicare requirements) who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem.

Medicare regulations at 42 CFR 410.32(a) state in part, that "…diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of

the beneficiary's specific medical problem." Thus, except where other uses have been authorized by statute, Medicare does not cover diagnostic testing used for routine screening or surveillance.

***Local Coverage Determination***

NGS LCD L36037 is available at NGS Medicare Medical Policy Center.

## PATIENT PRIVACY (HIPAA)

Under the Health Insurance Portability and Accountability Act (HIPAA), Aspenti is a health care provider and a covered entity. It is our policy to comply with the letter and intent of the HIPAA privacy and security standards. Our Privacy Policy, Notice of Privacy Practices, is available at www.aspenti.com.

## PROHIBITED REFERRALS & INDUCEMENTS

It is the policy of Aspenti to comply with all aspects of the laws and regulations governing physician self-referral, most noticeably the Stark Law. The Stark Law's self-referral ban states that if a financial relationship exists between a physician (or an immediate family member) and a laboratory (or certain other kinds of healthcare providers), and the relationship does not fit into one of the law's exceptions, then (a) the physician may not refer Medicare patients to the laboratory and (b) the laboratory may not bill Medicare for services referred by the physician. The kinds of relationships between laboratories and physicians that may be affected by these laws include the lease or rental of space or equipment and the purchase of medical or other services by a laboratory from a referring physician.

Federal Law, including the Anti-Kickback Statute, prohibits offering or paying remuneration-meaning anything of value to induce the referral of tests that are covered by Medicaid, Medicare or other federal health care programs. Any form of kickback, payment or other remuneration that is intended to secure the referral of federal health care program testing business is strictly prohibited and should be reported to the Aspenti Compliance Hotline by calling 781-222-5030.

**To avoid false claim submission, please be sure to:**
1. Order only those tests necessary for each patient's diagnosis or treatment. Each component of a panel must be necessary for the panel to qualify for Medicare reimbursement.
2. Provide a diagnosis for each test ordered.
3. Document this information in the patient's medical record followed by the ordering provider's signature.
4. Obtain an ABN from Medicare patients when tests do not meet the medical necessity criteria.

## MEDICARE RATES

Aspenti's currently provides testing described by the following CPT and HCPCS G-codes for 2020:

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| 2020 HCPCS Code | Short Description | 2019 Medicare Rate |
|---|---|---|
| 80307 | Drug test presumptive chemical analyzer | $ 64.95 |
| G0480 | Drug test definitive 1-7 classes | $ 114.43 |
| G0481 | Drug test definitive 8-14 classes | $ 156.59 |
| G0482 | Drug test definitive 15-21 classes | $ 198.74 |
| G0483 | Drug test definitive 22+ classes | $ 246.92 |

**Definitive Drug Classes & Corresponding 2020 AMA CPT Code**

(Tests may be ordered individually or included in the Definitive codes listed above)

| Drug Class | 2020 AMA CPT Code |
|---|---|
| Alcohols | 80320 |
| Alcohol biomarkers | 80321-80322 |
| Alkaloids, not otherwise specified | 80323 |
| Amphetamines | 80324-80326 |
| Anabolic steroids | 80327-80328 |
| Analgesics, non-opioid | 80329-80331 |
| Antidepressants, serotonergic class | 80332-80334 |
| Antidepressants, tricyclic and other cyclicals | 80335-80337 |
| Antidepressants, not otherwise specified | 80338 |
| Antiepileptics, not otherwise specified | 80339-80341 |
| Antipsychotics, not otherwise specified | 80342-80344 |
| Barbiturates | 80345 |
| Benzodiazepines | 80346-80347 |
| Buprenorphine | 80348 |
| Cannabinoids, natural | 80349 |
| Cannabinoids, synthetic | 80350-80352 |
| Cocaine | 80353 |
| Fentanyl | 80354 |
| Gabapentin, non-blood | 80355 |
| Heroin metabolite | 80356 |
| Ketamine and norketamine | 80357 |
| Methadone | 80358 |
| Methylenedioxyamphetamines (MDA, MDEA, MDMA) | 80359 |
| Methylphenidate | 80360 |
| Opiates | 80361 |
| Opioids and opiate analogs | 80362-80364 |
| Oxycodone | 80365 |
| Phencyclidine (PCP) | 83992 |
| Pregabalin | 80366 |
| Propoxyphene | 80367 |
| Sedative hypnotics (non-benzodiazepines) | 80368 |
| Skeletal muscle relaxants | 80369-80370 |

| | |
|---|---|
| Stimulants, synthetic | 80371 |
| Tapentadol | 80372 |
| Tramadol | 80373 |
| Urine pregnancy test (CLIA-waived) | 81025 |

Medicare Clinical Laboratory Fee Schedules showing the maximum Medicare reimbursement for these tests are available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files.html.