Reimbursement Policy

Serum Testing for Evidence of Mild Traumatic Brain Injury

I. Policy Description

Traumatic brain injury (TBI) is characterized by pathologic injuries to the brain resulting from external forces or trauma. A broad range of sequela of varying clinical severity include focal contusions and hematomas, diffuse axonal injury, cerebral edema and swelling, and a cascade of molecular injury mechanisms.[1]

Concussion refers to the trauma-induced alteration in mental status, which may or may not involve loss of consciousness, after a mild TBI.[2] Measurement of blood and other fluid biomarkers has been proposed as a way of evaluating mild traumatic brain injury.

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

1. For the evaluation of mild traumatic brain injury (TBI), measurement of concussion markers (e.g., S100B, GFAP, and UCH-L1) in the blood, saliva, and/or cerebrospinal fluid (CSF) **DOES NOT MEET COVERAGE CRITERIA.**

2. Panels designed to measure biomarkers of TBI (e.g., i-STAT TBI Plasma, Alinity® i TBI) **DO NOT MEET COVERAGE CRITERIA.**

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: http://www.cms.gov/medicare-

coverage-database/overview-and-quick-search.aspx. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

On Jan 8, 2021, with 510(K) clearance, the FDA approved marketing of i-STAT TBI Plasma Cartridge with the i-STAT™ Alinity™ System from Abbott Laboratories. This brain trauma assessment test is intended for *in vitro* diagnostic use to aid in evaluating patients, 18 years of age or older, with suspected mTBI (Glasgow Coma Scale score 13-15) within 12 hours of injury with other clinical information to assess the need for radiologic imaging (CT, MRI). A result from this test is associated with the absence or presence of acute traumatic intracranial lesions seen on a head CT scan, but is not intended for use in point of care settings.[49] In March 2023, the FDA approved Abbott's Alinity® i TBI lab test as a complement to the i-STAT™ Alinity™ System. According to Abbott, the test measures ubiquitin C-terminal hydrolase L1 (UCH-L1) and GFAP; the test assesses whether there are elevated concentrations of these biomarkers in the blood. While the i-STAT™ Alinity™ System is the first rapid hand-held test that measures biomarkers in plasma, the Alinity® i TBI test is a blood test run on Abbott's Alinity® i instrument.[35]

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
83516	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method
84999	Unlisted chemistry procedure
0570U	Neurology (traumatic brain injury), analysis of glial fibrillary acidic protein (GFAP) and ubiquitin carboxylterminal hydrolase L1 (UCHL1), immunoassay, whole blood or plasma, individual components reported with the overall result of elevated or non-elevated based on threshold comparison Proprietary test: i-STAT TBI Lab/Manufacturer: Abbott Point of Care

Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

V. Evidence-based Scientific References

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VI. Revision History

Revision Date	Summary of Changes
06/04/2025	Reviewed and Updated: Updated the background, guidelines and recommendations, and evidence-based scientific references. Literature review did not necessitate any modifications to coverage criteria. The following changes were made for clarity and consistency:

Reimbursement Policy

	Panel testing moved from CC1 into new CC2 for clarity. New CC2 now reads: "2) Panels designed to measure biomarkers of TBI (e.g., i-STAT TBI Plasma, Alinity® i TBI) DO NOT MEET COVERAGE CRITERIA." Added CPT code 0570U (effective date 7/1/2025)