of Tennessee

Policy

Reimbursement Policy

Therapeutic Drug Monitoring for 5-Fluorouracil

I. Policy Description

Chemotherapeutic agents are incredibly potent drugs, often carrying cytotoxic side effects. Most chemotherapeutic drugs have a steep dose-response relationship and a narrow therapeutic index (a range where an agent provides therapeutic effect without major side effects). Identification of the optimal dose of a chemotherapeutic agent, such as 5-fluorouracil, has been proposed as a potential improvement for the management of cancer patients (Eaton, 2024).

This policy does not address pharmacogenetic testing to aid or direct chemotherapies. For pharmacogenetic testing, please refer to AHS-M2021.

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.

1) For individuals who are undergoing 5-fluorouracil chemotherapy, therapeutic drug monitoring (TDM) to aid in managing dose adjustment **MEETS COVERAGE CRITERIA**.

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.

2) To aid in managing dose adjustment for individuals undergoing 5-fluorouracil chemotherapy, the following tests **DO NOT MEET COVERAGE CRITERIA**:
   a) Uracil breath tests.
   b) Dihydrouracil/uracil ratio testing of plasma, serum, or urine samples.

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: https://www.cms.gov/medicare-coverage-database/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.

The FDA's "Prescribing Information" documents for fluorouracil, paclitaxel, imatinib, and docetaxel do not include AUC as a method to adjust dosage (FDA, 2016a, 2016b, 2018, 2021).

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
S3722	Dose optimization by area under the curve (AUC) analysis, for infusional 5-fluorouracil
80299	Quantitation of therapeutic drug, not elsewhere specified
82542	Column chromatography, includes mass spectrometry, if performed (e.g., HPLC, LC, LC/MS, LC/MS-MS, GC, GC/MS-MS, GC/MS, HPLC/MS), non-drug analyte(s) not elsewhere specified, qualitative or quantitative, each specimen
83789	Mass spectrometry and tandem mass spectrometry (e.g., MS, MS/MS, MALDI, MS-TOF, QTOF), non-drug analyte(s) not elsewhere specified, qualitative or quantitative, each specimen

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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