Status
Active

BlueCross BlueShield Minnesota

Medical and Behavioral Health Policy
Section: Laboratory
Policy Number: VI-30
Effective Date: 02/26/2014

IN VITRO CHEMORESISTANCE AND CHEMOSENSITIVITY ASSAYS

Description: In vitro chemoresistance and chemosensitivity assays have been investigated as a means of predicting tumor response to various chemotherapies. A variety of assays have been developed that differ in their processing and in the technique used to measure the sensitivity or resistance. However, all assays involve the same four basic steps: isolation of cells; incubation of cells with drugs; assessment of cell survival; and interpretation of the result. Results may be reported as either drug sensitive, drug resistant, or intermediate.

Use of a chemosensitivity assay is proposed as a method of identifying the effect of specific chemotherapy drugs on the tumor(s) of an individual patient, resulting in potential selection of the most appropriate treatment regimen. With this type of assay, tumor cells from the patient are cultured and exposed to specific drugs in the laboratory setting for a given period of time to evaluate survival and sensitivity of the tumor cells to the drugs. The histoculture drug response assay (AntiCancer, Inc.) is a type of commercially-available chemosensitivity assay.

Chemoresistance assays, by contrast, seek to identify chemotherapy drugs that would be potentially ineffective in a given patient. The Oncotech Extreme Drug Resistance (EDR®) assay (Exiqon Diagnostics) is one example of this type of testing. In this assay, cultured cells are exposed to high concentrations of specific chemotherapy drugs for prolonged periods. Cell lines that survive this exposure are described as showing extreme drug resistance and, as a result, are considered potentially ineffective for that patient.

The ChemoFx® assay (Precision Therapeutics, Inc) is intended to measure both sensitivity and resistance of tumor cells to chemotherapy agents. In this automated test, cultured tumor cells prepared from a surgical specimen are exposed to various

concentrations of the chemotherapy agents under consideration and the percentage of killed cells for each challenge is determined.

Policy: In vitro chemosensitivity assays and in vitro chemoresistance assays are considered **INVESTIGATIVE** due to a lack of clinical evidence indicating a statistically significant impact on improved health outcomes.

Coverage: Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member's summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

Coding: *The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.*

The drug resistance assay is a multistep laboratory procedure identified by the following CPT codes:

CPT:

87230 Toxin or antitoxin assay, tissue culture

88104 Cytopathology, fluids, washings or brushings; except cervical or vaginal; smears with interpretation

88305 Level IV surgical pathology, gross and microscopic examination

88313 Special stains; Group II, all other (eg, iron, trichrome), except immunocytochemistry and immunoperoxidase stains, including interpretation and report, each

88358 Morphometric analysis; tumor (eg, DNA ploidy)

89050 Cell count, miscellaneous body fluids (eg, cerebrospinal fluid, joint fluid), except blood

Policy History:

Developed May 13, 2009

Most recent history:
Reviewed February 9, 2011
Reviewed February 8, 2012
Reviewed February 13, 2013
Reviewed February 12, 2014

Cross Reference: