BlueCross BlueShield of Illinois

If a conflict arises between a Clinical Payment and Coding Policy ("CPCP") and any plan document under which a member is entitled to Covered Services, the plan document will govern. If a conflict arises between a CPCP and any provider contract pursuant to which a provider participates in and/or provides Covered Services to eligible member(s) and/or plans, the provider contract will govern. "Plan documents" include, but are not limited to, Certificates of Health Care Benefits, benefit booklets, Summary Plan Descriptions, and other coverage documents. BCBSIL may use reasonable discretion interpreting and applying this policy to services being delivered in a particular case. BCBSIL has full and final discretionary authority for their interpretation and application to the extent provided under any applicable plan documents.

Providers are responsible for submission of accurate documentation of services performed. Providers are expected to submit claims for services rendered using valid code combinations from Health Insurance Portability and Accountability Act ("HIPAA") approved code sets. Claims should be coded appropriately according to industry standard coding guidelines including, but not limited to: Uniform Billing ("UB") Editor, American Medical Association ("AMA"), Current Procedural Terminology ("CPT®"), CPT® Assistant, Healthcare Common Procedure Coding System ("HCPCS"), ICD-10 CM and PCS, National Drug Codes ("NDC"), Diagnosis Related Group ("DRG") guidelines, Centers for Medicare and Medicaid Services ("CMS") National Correct Coding Initiative ("NCCI") Policy Manual, CCI table edits and other CMS guidelines.

Claims are subject to the code edit protocols for services/procedures billed. Claim submissions are subject to claim review including but not limited to, any terms of benefit coverage, provider contract language, medical policies, clinical payment and coding policies as well as coding software logic. Upon request, the provider is urged to submit any additional documentation.

In Vitro Chemoresistance and Chemosensitivity Assays

Policy Number: CPCPLAB030

Version 1.0

Enterprise Medical Policy Committee Approval Date: January 25, 2022

Plan Effective Date: May 1, 2022

Description

BCBSIL has implemented certain lab management reimbursement criteria. Not all requirements apply to each product. Providers are urged to review Plan documents for eligible coverage for services rendered.

Reimbursement Information:

1. In vitro chemosensitivity assays, including, but not limited to, the histoculture drug response assay or a fluorescent cytoprint assay, **is not reimbursable.**

2. In vitro chemoresistance assays, including, but not limited to, extreme drug resistance (EDR) assays, **is not reimbursable**.

Procedure Codes

Codes
81535, 81536, 86849, 88104, 88199, 88305, 88313, 88358, 89050, 89240, 0564T, 0083U, 0284U

References:

Brower, S. L., Fensterer, J. E., & Bush, J. E. (2008). The ChemoFx® Assay: An Ex Vivo Chemosensitivity and Resistance Assay for Predicting Patient Response to Cancer Chemotherapy. In G. Mor & A. B. Alvero (Eds.), *Apoptosis and Cancer: Methods and Protocols* (pp. 57-78). Totowa, NJ: Humana Press.

Burstein, H. J., Mangu, P. B., Somerfield, M. R., Schrag, D., Samson, D., Holt, L., . . . Ajani, J. A. (2011). American Society of Clinical Oncology clinical practice guideline update on the use of chemotherapy sensitivity and resistance assays. *J Clin Oncol, 29*(24), 3328-3330. doi:10.1200/jco.2011.36.0354

Chen, Z., Zhang, S., Ma, S., Li, C., Xu, C., Shen, Y., Zhao, J., & Miao, L. (2018). Evaluation of the in vitro Chemosensitivity and Correlation with Clinical Outcomes in Lung Cancer using the ATP-TCA. *Anticancer Agents Med Chem*, *18*(1), 139-145. https://doi.org/10.2174/1871520617666170419123713

CMS. (2021). *Medicare Coverage Database* https://www.cms.gov/medicare-coverage-database/new-search/search.aspx

FDA. (2021). Devices@FDA. Retrieved from https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm

Grendys, E. C., Jr., Fiorica, J. V., Orr, J. W., Jr., Holloway, R., Wang, D., Tian, C., . . . Herzog, T. J. (2014). Overview of a chemoresponse assay in ovarian cancer. *Clin Transl Oncol, 16*(9), 761-769. doi:10.1007/s12094-014-1192-8

Hatok, J., Babusikova, E., Matakova, T., Mistuna, D., Dobrota, D., & Racay, P. (2009). In vitro assays for the evaluation of drug resistance in tumor cells. *Clin Exp Med, 9*(1), 1-7. doi:10.1007/s10238-008-0011-3

Hoffman, R. M. (2018). Clinical Correlation of the Histoculture Drug Response Assay in Gastrointestinal Cancer. *Methods Mol Biol, 1760*, 61-72. doi:10.1007/978-1-4939-7745-1_7

Howard, C. M., Valluri, J., Alberico, A., Julien, T., Mazagri, R., Marsh, R., . . . Claudio, P. P. (2017). Analysis of Chemopredictive Assay for Targeting Cancer Stem Cells in Glioblastoma Patients. *Transl Oncol, 10*(2), 241-254. doi:10.1016/j.tranon.2017.01.008

KIYATEC. (2021). http://kiyatec.com/

Krivak, T. C., Lele, S., Richard, S., Secord, A. A., Leath, C. A., 3rd, Brower, S. L., . . . Moore, R. G. (2014). A chemoresponse assay for prediction of platinum resistance in primary ovarian cancer. *Am J Obstet Gynecol, 211*(1), 68.e61-68. doi:10.1016/j.ajog.2014.02.009

Kwon, H. Y., Kim, I. K., Kang, J., Sohn, S. K., & Lee, K. Y. (2016). In Vitro Adenosine Triphosphate-Based Chemotherapy Response Assay as a Predictor of Clinical Response to Fluorouracil-Based Adjuvant Chemotherapy in Stage II Colorectal Cancer. *Cancer Res Treat, 48*(3), 970-977. doi:10.4143/crt.2015.140

NCCN. (2021a). NCCN Clinical Practice Guidelines in Oncology. *NCCN Clinical Practice Guidelines in Oncology.* Retrieved from https://www.nccn.org/professionals/physician_gls/default.aspx

NCCN. (2021b). NCCN Clinical Practice Guidelines in Oncology; Ovarian Cancer v 1.2020. Retrieved from https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf

Pierian. (2021). Products: ChemoINTEL™. Retrieved from https://pierianbio.com/project/chemo-intel/

RGCC. (2021). Onconomics RGCC. Retrieved from http://www.rgcc-group.com/tests/onconomics-rgcc/

Rutherford, T., Orr, J., Jr., Grendys, E., Jr., Edwards, R., Krivak, T. C., Holloway, R., . . . Herzog, T. J. (2013). A prospective study evaluating the clinical relevance of a chemoresponse assay for treatment of patients with persistent or recurrent ovarian cancer. *Gynecol Oncol, 131*(2), 362-367. doi:10.1016/j.ygyno.2013.08.009

Schrag, D., Garewal, H. S., Burstein, H. J., Samson, D. J., Von Hoff, D. D., & Somerfield, M. R. (2004). American Society of Clinical Oncology Technology Assessment: chemotherapy sensitivity and resistance assays. *J Clin Oncol, 22*(17), 3631-3638. doi:10.1200/jco.2004.05.065

Strickland, S. A., Raptis, A., Hallquist, A., Rutledge, J., Chernick, M., Perree, M., . . . Presant, C. A. (2013). Correlation of the microculture-kinetic drug-induced apoptosis assay with patient outcomes in initial treatment of adult acute myelocytic leukemia. *Leuk Lymphoma, 54*(3), 528-534. doi:10.3109/10428194.2012.722217

Tatar, B., Boyraz, G., Selçuk, İ., Doğan, A. K., Usubütün, A., & Tuncer, Z. S. (2016). In vitro chemosensitivity in ovarian carcinoma: Comparison of three leading assays. In *J Turk Ger Gynecol Assoc* (Vol. 17, pp. 35-40).

Theralink. (2021). Theralink: Precision Medicine for Life. https://theralink.com/

Policy Update History:

5/1/2022	New policy