Medical Policy
InVitro Chemoresistance and Chemosensitivity Assays

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Policy Number: 253
BCBSA Reference Number: 2.03.01

Related Policies
None

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members
In vitro chemosensitivity assays, including but not limited to histoculture drug response assays or fluorescent cytoprint assays, are INVESTIGATIONAL.

In vitro chemoresistance assays, including but not limited to extreme drug resistance assays, are INVESTIGATIONAL.

Prior Authorization Information
Commercial Members: Managed Care (HMO and POS)
This is NOT a covered service.

Commercial Members: PPO, and Indemnity
This is NOT a covered service.

Medicare Members: HMO BlueSM
This is NOT a covered service.

Medicare Members: PPO BlueSM
This is NOT a covered service.

CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.
Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

**CPT Codes**
There is no specific CPT code for this service.

**ICD-9 Diagnosis Codes**
Investigational for all diagnoses.

**Description**
In vitro chemoresistance and chemosensitivity assays have been developed as a means of predicting tumor response to various chemotherapies. These assays are sometimes used by oncologists to select treatment regimens for an individual patient. Several assays have been developed that differ with respect to processing of biological samples and detection methods. All assays involve similar principles and they share protocol components including:
- Isolation of cells and establishment in an in vitro medium (sometimes in soft agar)
- Incubation of the cells with various drugs
- Assessment of cell survival, and
- Interpretation of the result.

A variety of chemosensitivity and chemoresistance assays have been clinically evaluated in human trials to assess cell survival following exposure to a drug of interest.

Examples of chemosensitivity and chemoresistance assays for predicting tumor response to various chemotherapies include, Extreme Drug Resistance Assay (EDR®) from Exiqon Diagnostics, Histoculture Drug Resistance Assay (HDRA) from AntiCancer, Inc. and Adenosine Triphosphate (ATP) Bioluminescence Assay (ChemoFX®) from Precision Therapeutics. All chemosensitivity and chemoresistance assays for predicting tumor response to various chemotherapies are considered investigational regardless of the commercial name, the manufacturer or FDA approval status.

**Summary**
There have been no studies published with a randomized, prospective, design to evaluate this testing. The clinical utility of chemoresistance and chemosensitivity assays has not been determined, and data are insufficient to determine whether use of the test to select chemotherapy regimens for individual patients will improve outcomes. Therefore, this testing is considered investigational.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>7/2014</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>5/2013</td>
<td>New references from BCBSA National medical policy.</td>
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<td>8/1/2011</td>
<td>Reviewed- Medical Policy Group– Hematology and Oncology</td>
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<tr>
<td>12/1/2010</td>
<td>New policy describing ongoing non-</td>
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**Information Pertaining to All Blue Cross Blue Shield Medical Policies**
Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines
References


