**HUMAN TUMOR STEM CELL DRUG SENSITIVITY ASSAYS (NCD 190.7)**

**Guideline Number:** MPG145.03  
**Approval Date:** January 10, 2018

### TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®**), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use and distribution of this information are strictly prohibited.

*For more information on a specific member’s benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.  
**CPT® is a registered trademark of the American Medical Association.

### PURPOSE

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

---

**Table of Contents**

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>TERMS AND CONDITIONS</td>
<td>1</td>
</tr>
<tr>
<td>PURPOSE</td>
<td>1</td>
</tr>
<tr>
<td>POLICY SUMMARY</td>
<td>2</td>
</tr>
<tr>
<td>APPLICABLE CODES</td>
<td>2</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>2</td>
</tr>
<tr>
<td>GUIDELINE HISTORY/REVISION INFORMATION</td>
<td>3</td>
</tr>
</tbody>
</table>

**Related Medicare Advantage Policy Guidelines**

- Molecular Pathology/Molecular Diagnostics/Genetic Testing

**Related Medicare Advantage Coverage Summary**

- Laboratory Tests and Services
UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

**POLICY SUMMARY**

**Overview**
Human tumor stem cell drug sensitivity assays involve exposure of human tumor stem cell colonies grown in tissue culture to anticancer drugs and observing for cytotoxic effects. Their purpose is to screen potential anticancer drugs and predict the effects of these drugs on tumors of individual patients, to allow the selection of the most effective drug or drugs for that patient.

The Fluorescent Cytoprint Assay, a miniaturized organ culture system for cancer chemosensitivity testing, allows for qualitative visual estimation of cell kill using low power microscopy and a noncytotoxic fluorescence probe for cell viability.

**Guidelines**
Human tumor drug sensitivity assays are considered experimental, and therefore, not covered under Medicare at this time.

The clinical application of the assay, based on testing in tumor microorgans rather than in clones derived from single cells, is considered experimental, and therefore, not covered under Medicare at this time.

**APPLICABLE CODES**

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>84999</td>
<td>Unlisted chemistry procedure</td>
</tr>
<tr>
<td>86849</td>
<td>Unlisted immunology procedure</td>
</tr>
</tbody>
</table>

*CPT® is a registered trademark of the American Medical Association*

**REFERENCES**

**CMS National Coverage Determinations (NCDs)**
NCD 190.7 Human Tumor Stem Cell Drug Sensitivity Assays

**CMS Local Coverage Determinations (LCDs)**

<table>
<thead>
<tr>
<th>LCD</th>
<th>Medicare Part A</th>
<th>Medicare Part B</th>
</tr>
</thead>
</table>

**CMS Benefit Policy Manual**
Chapter 15; § 80 - 80.1.3 Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests

**CMS Claims Processing Manual**
Chapter 16; § 20-40 Calculation of Payment Rates – Clinical Laboratory Test Fee Schedules, Special Payment Considerations, Billing for Clinical Laboratory Tests; § 70 Clinical Laboratory Improvement Amendments (CLIA) Requirements

**UnitedHealthcare Commercial Policies**
Chemosensitivity and Chemoresistance Assays in Cancer

**Others**
American Society of Clinical Oncology Clinical Practice Guideline Update on the Use of Chemotherapy Sensitivity and Resistance Assays

Human Tumor Stem Cell Drug Sensitivity Assays (NCD 190.7) UnitedHealthcare Medicare Advantage Policy Guideline Page 2 of 3
Proprietary Information of UnitedHealthcare. Copyright 2018 United HealthCare Services, Inc.
Revisions to this summary document do not in any way modify the requirement that services be provided and
documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/10/2018</td>
<td>• Annual review MAPG Committee presentation and approval</td>
</tr>
</tbody>
</table>