Coverage Summary

Laboratory Tests and Services

Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee  Last Review Date: 10/20/2020

Related Medicare Advantage Policy Guidelines:

- Clinical Diagnostic Laboratory Services
- Histocompatibility Testing (NCD 190.1)
- Human Tumor Stem Cell Drug Sensitivity Assays (NCD 190.7)
- Lymphocyte Mitogen Response Assays (NCD 190.8)
- Obsolete or Unreliable Diagnostic Tests (NCD 300.1)

- Pharmacogenomic Testing for Warfarin Response (NCD 90.1)
- Qualitative Drug Testing for Indications Other Than Mental Health
- Serologic Testing for Acquired Immunodeficiency Syndrome (AIDS) (NCD 190.9)
- Vitamin D Testing

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The benefit information in this Coverage Summary is based on existing national coverage policy, however Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

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**I. COVERAGE**

**Coverage Statement:** Laboratory tests and services are covered when Medicare coverage criteria are met.

**COVID-19 Public Health Emergency Waivers & Flexibilities:** In response to the COVID-19 Public Health Emergency, CMS has updated some guidance for certain laboratory services. For details, see the following Coronavirus Waivers/Flexibilities: [Laboratories (PDF)].

Guidelines/Notes:

1. Laboratory services (inpatient or outpatient) are covered in support of basic health care services to be used in the screening or detection of disease and determined to be reasonable and medically necessary.

   See the Medicare Benefit Policy Manual, Chapter 15, §80.1 – Clinical Laboratory Services. (Accessed April 15, 2020)

   For quality standards for all laboratory testing, see the Medicare Clinical Laboratory Improvement Amendments (CLIA) website at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html. (Accessed April 15, 2020)

2. The following clinical diagnostic laboratory tests and services are covered when Medicare criteria are met. Applicable NCDs for these tests are available at the Lab National Coverage Determinations (NCDs) Alphabetical Index. (Accessed April 15, 2020)

   a. Alpha-fetoprotein; see the Coverage Summary for Genetic Testing
   b. Blood Counts; see the NCD for Blood Counts (190.15)
   c. Blood Glucose Testing; see the NCD for Blood Glucose Testing (190.20)
   d. Carcinoembryonic Antigen; see the NCD for Carcinoembryonic Antigen (CEA) (190.26)
   e. Collagen Cross Link; see the NCD for Collagen Crosslinks, any Method (190.19)
   f. Digoxin Therapeutic Drug Assay; see the NCD for Digoxin Therapeutic Drug Assay (190.24)
   g. Fecal Occult Blood Test; see the Coverage Summary for Preventive Health Services and Procedures
   h. Gamma Glutamyl Transferase; see the NCD for Gamma Glutamyl Transferase (GGT) (190.32)
   i. Glycated Hemoglobin/Glycated Protein; see the NCD for Glycated Hemoglobin/Glycated Protein (190.21)
   j. Hepatitis Panel; see the NCD for Hepatitis Panel/Acute Hepatitis Panel (190.33)
   k. Human Chorionic Gonadotropin (hCG); see the NCD for Human Chorionic Gonadotropin (hCG) (190.27)
   l. HIV testing (Diagnosis); see the NCD for Human Immunodeficiency Virus (HIV) Testing (Diagnosis) (190.14)
   m. HIV Testing (Prognosis and Monitoring); see the NCD for Human Immunodeficiency Virus (HIV) Testing (Prognosis Including Monitoring) (190.13)
   n. Lipid Testing; see the NCD for Lipid Testing (190.23)
   o. PTT (Partial Thromboplastin Time); see the NCD for Partial Thromboplastin Time (PTT) (190.16)
   p. Prostate Specific Antigen; see the Coverage Summary for Genetic Testing
   q. Prothrombin Test; see the NCD for Prothrombin Time (PT) (190.17)
   r. Serum Iron Studies; see the NCD for Serum Iron Studies (190.18)
   s. Thyroid Testing; see the NCD for Thyroid Testing (190.22)
   t. Tumor Antigen by Immunoassay-CA 125; see the Coverage Summary for Genetic Testing
   u. Tumor Antigen by Immunoassay-CA 15-3/CA 27.29; see the Coverage Summary for Genetic Testing
   v. Tumor Antigen by Immunoassay-CA 19-9; see the Coverage Summary for Genetic Testing
   w. Urine Culture, Bacterial; see the NCD for Urine Culture, Bacterial (190.12)
3. **Other Laboratory Tests and Services**
   a. **Home Blood Draws (Venipunctures)**
      Medically necessary home blood draws (venipunctures) by an independent laboratory technician are covered in the following circumstances:
      - Patient is confined to home or other place of residence used as his or his home when the specimen is a type which would require the skills of a laboratory technician (e.g., where a laboratory technician draws a blood specimen). For definition of homebound, see the [Medicare Benefit Policy Manual, Chapter 7, §30.1.1 – Patient Confined to the Home](https://www.cms.gov/medicare-benefit-policy-manual). (Accessed April 16, 2020)
      - Patient’s place of residence is an institution, only if:
        - The patient was confined to the facility; and
        - The facility did not have on duty personnel qualified to perform the service.

      **Note:** Specimen which would require only the services of a messenger and would not require the skills of a laboratory technician (e.g., urine or sputum), a specimen pickup service would not be considered medically necessary.


   b. **Molecular Diagnostic Tests (MDT); see the Coverage Summary for Genetic Testing**

   c. **Vitamin D Assays (CPT code 82306)**
      - Medicare does not have a National Coverage Determination (NCD) for Vitamin D Assays.
      - Local Coverage Determinations (LCDs)/Local Coverage Article (LCAs) exist for all states/territories and compliance with these policies is required where applicable.
        For specific LCDs/LCAs, refer to the [LCD/LCA Availability Grid (Attachment A)](https://www.cms.gov/medicare-benefit-policy-manual).  
      - Committee approval date: April 21, 2020
      - Accessed January 25, 2021

   d. **B-type Natriuretic Peptide (BNP) Measurements (CPT code 83880)**
      - Medicare does not have a National Coverage Determination (NCD) for B-type Natriuretic Peptide (BNP) measurements.
      - Local Coverage Determinations (LCDs)/Local Coverage Article (LCAs) exist for all states/territories and compliance with these policies is required where applicable.
        For specific LCDs/LCAs, refer to the [LCD/LCA Availability Grid (Attachment B)](https://www.cms.gov/medicare-benefit-policy-manual). 
      - Committee approval date: August 18, 2020
      - Accessed January 25, 2021

   e. **Chemosensitivity and Chemoresistance Assays (CSRAs)**
      1) **Human Tumor Stem Cell Drug Sensitivity Assay**
         The NCD for Human Tumor Stem Cell Drug Sensitivity Assay (190.7) addresses 2 distinct types of assays:
         - Human Tumor stem cell drug sensitivity assays, and
         - Fluorescent Cytoprint Assays.

         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.


         2) **Other Chemosensitivity and Chemoresistance Assays (CSRAs)**
         Examples include but are not limited to Oncotech Extreme Drug Resistance (EDR)
assay, DiSC (Differential staining cytotoxicity) assay, ATP (Adenosine Triphosphate) assay, MTT (Methyl Thiazolyl Tetrazolium) assay, HYDRA® (AntiCancer inc) assay, EVA-PCD (Rational Therapeutics) assay, and ChemoFx® assay.

- Medicare does not have a National Coverage Determination (NCD) for CSRAs.
- Local Coverage Determinations (LCDs)/Local Coverage Article (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the LCD/LCA Availability Grid (Attachment C).
- For coverage guidelines for states/territories with no LCDs/LCAs, see the UnitedHealthcare Commercial Medical Policy for Chemosensitivity and Chemoresistance Assays in Cancer. (IMPORTANT NOTE: After checking the LCD/LCA Availability Grid and searching the Medicare Coverage Database, if no LCD/LCA is found, then use the above referenced policy.)
- Committee approval date: April 21, 2020
  - Accessed January 25, 2021

f. HIV Serologic Testing; see the NCD for Serologic Testing for Acquired Immunodeficiency Syndrome (AIDS) (190.9). (Accessed April 15, 2020)

g. Sweat Test for Diagnosis of Cystic Fibrosis; see the NCD for Sweat Test (190.5) (Accessed April 15, 2020)

4. Other laboratory tests and services that are not covered include, but are not limited to:
   a. Obsolete and unreliable diagnostic tests; see the NCD for Obsolete or Unreliable Diagnostic Tests (300.1). (Accessed April 16, 2020)
   b. Hair analysis; see the NCD for Hair Analysis (190.6). (Accessed April 10, 2018)
   d. Employer or legally required drug or alcohol testing; see the Medicare Benefit Policy Manual, Chapter 16, §20 – Services Not Reasonable and Necessary. (Accessed April 16, 2020)
   e. Genetic testing to determine predisposition to an inherited disease (carrier status) or when the test will not be used to determine the care of member; see the Medicare Benefit Policy Manual, Chapter 16, §20 – Services Not Reasonable and Necessary. (Accessed April 16, 2020)

Also see the Coverage Summary for Genetic Testing.

f. Serum testing for genetic predisposition for Huntington’s Chorea; see the Medicare Benefit Policy Manual, Chapter 16, §20 – Services Not Reasonable and Necessary. (Accessed April 16, 2020)

Also see Coverage Summary for Genetic Testing.

g. Pre-marital blood testing; see the Medicare Benefit Policy Manual, Chapter 16, §20 – Services Not Reasonable and Necessary. (Accessed April 16, 2020)

h. School admissions and athletic requirement for laboratory testing; see the Medicare Benefit Policy Manual, Chapter 16, §20 – Services Not Reasonable and Necessary. (Accessed April 16, 2020)

i. Cytotoxic food tests; see the NCD for Cytotoxic Food Tests (110.13). (Accessed April 16, 2020)

Also see the Coverage Summary for Allergy Testing and Allergy Immunotherapy.

j. Heartsbreath test for heart transplant rejection; see the NCD for Heartsbreath Test for Heart Transplant Rejection (260.10). (Accessed April 16, 2020)

Also see the Coverage Summary for Preventive Health Services and Procedures and the
II. DEFINITIONS

**Laboratory**: Any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. *Medicare Benefit Policy Manual, Chapter 15, §80.1 – Clinical Laboratory Services*, (Accessed April 16, 2020)

III. REFERENCES

IV. REVISION HISTORY

10/20/2020  Coverage Statement
- Updated notation pertaining to COVID-19 Public Health Emergency Waivers & Flexibilities to indicate:
  - In response to the COVID-19 Public Health Emergency, the Centers for Medicare & Medicaid Services (CMS) has updated some guidance for certain laboratory services; for details, see the Coronavirus Waivers & Flexibilities: Laboratories

V. ATTACHMENTS

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<tr>
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*Note: States notated with an asterisk should follow the other available state-specific
### Attachment A – LCD/LCA Availability Grid

**Vitamin D Assay Test**

CMS website accessed January 25, 2021

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End of Attachment A

### Attachment B – LCD/LCA Availability Grid

**B-type Natriuretic Peptide (BNP) Measurements**

CMS website accessed January 25, 2021

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**Note:** States notated with an asterisk should follow the other available state-specific LCD/LCA listed on this grid. This WPS LCD/LCA only applies to states without asterisk.

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End of Attachment C