

Cell Enumeration, Medical 310

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Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details ^{*}.

Purpose:

This policy addresses the medical necessity of - Cell Enumeration

Description & Definitions:

Cell enumeration lab test that counts tumor cells isolated from a blood sample and reporting findings such as malignant cells.

Criteria:

Cell Enumeration is considered not medically necessary for any indication.

Coding:

Medically necessary with criteria:

Coding	Description
	None

Considered Not Medically Necessary:

Coding	Description
86152	Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood)
86153	Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood); physician interpretation and report, when required

0091U	Oncology (colorectal) screening, cell enumeration of circulating tumor cells, utilizing whole blood, algorithm, for the presence of adenoma or cancer, reported as a positive or negative result
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U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2020: January
- 2016: January, April
- 2015: January, February, October
- 2014: July, December
- 2013: January, February, March, July, August, September

Reviewed Dates:

- 2024: May
- 2022: May
- 2021: May
- 2020: June
- 2019: June
- 2018: April
- 2016: June, July

Effective Date:

- December 2012

References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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Sec. 864.5220 Automated differential cell counter. (2023, Dec 22). Retrieved Apr 12, 2024, from Code of Federal Regulations: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm?fr=864.5220>

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Special Notes: *

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

Keywords:

SHP Cell Enumeration, SHP Medical 310, counting, cell sample, reports, malignant cells, CellSearch Circulating Tumor Cell Kit, CellTracks AutoPrep System, CellTracks Analyzer II, CellSearch CTC Epithelial Cell Kit, CTC, CellSearch Epithelial Cell Kit, MagNest Cell Preservation Device, CellSpotter Analyzer, CellSave Preservative Tube, Janssen Diagnostics LLC, Veridex LLC, CellTracks Analyzer, CellSearch Tumor Phenotyping Reagent HER2,

