



Cell Enumeration, Medical 310

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<u>Purpose</u> <u>Description & Definitions</u> <u>Criteria</u>	<u>Next Review Date</u>	5/14/2025
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All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual <u>*</u>.

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 nec	essary with criteria:	
Coding	Description	
	None	
Considered N	lot 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

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:

Including but not limited to: 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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(2024). Retrieved Apr 12, 2024, from Department of Medical Assistance Services - MES Public Portal: <u>https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-</u> <u>library#gsc.tab=0&gsc.q=Cell%20enumeration&gsc.sort=</u>

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Oncotype DX AR-V7 Nucleus Detect (Epic Sciences). (2023, Aug 04). Retrieved Apr 10, 2024, from Hayes: <u>https://evidence.hayesinc.com/report/mta.oncotypedxarv74857</u>

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

Yamashita, T., & Shirali, A. (2024, Jan). Is there a role for liquid biopsy in the surveillance of parathyroid carcinoma? Retrieved Apr 12, 2024, from PubMed: <u>https://pubmed.ncbi.nlm.nih.gov/37993289/</u>

Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

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.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

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, FirstSightCRC, CellMax Life.