

## Agile Patency System

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<u>Effective Date</u>	4/2008
<u>Next Review Date</u>	1/2024
<u>Coverage Policy</u>	Medical 131
<u>Version</u>	4

**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.\*.**

**Purpose:**

This policy addresses the medical necessity of Agile Patency System.

**Description & Definitions:**

Agile Patency System is a diagnostic testing with the use of a biodegradable capsule that is swallowed to allow physicians to determine patency of the gastrointestinal tract if an individual should undergo a capsule endoscopy, making sure the capsule is eliminated.

**Criteria:**

Agile Patency System is considered not medically necessary for any indication.

**Coding:**

Medically necessary with criteria:

Coding	Description
	None

Considered Not Medically Necessary:

Coding	Description
91299	Unlisted diagnostic gastroenterology procedure

U.S. Food and Drug Administration (FDA) - approved only products only.

## Document History:

### Revised Dates:

- 2019: November (unarchived)
- 2016: January, March, April
- 2015: June (archived-became part of Medical 81)

### Reviewed Dates:

- 2023: January
- 2022: February
- 2021: February
- 2020: March
- 2018: November
- 2017: November
- 2016: June
- 2014: June
- 2013: June
- 2012: June
- 2011: July
- 2010: June
- 2009: April

### Effective Date:

- April 2008

## 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).

(2022). Retrieved Dec 1, 2022, from National Comprehensive Cancer Network:  
[https://www.nccn.org/professionals/physician\\_gls/pdf/small\\_bowel.pdf](https://www.nccn.org/professionals/physician_gls/pdf/small_bowel.pdf)

(2022). Retrieved Nov 30, 2022, from MCG 26th Edition: <https://careweb.careguidelines.com/ed26/index.html>

(2022). Retrieved Dec 1, 2022, from AIM Specialty Health:  
[https://guidelines.aimspecialtyhealth.com/?s=patency+capsule&et\\_pb\\_searchform\\_submit=et\\_search\\_process&et\\_pb\\_search\\_cat=11%2C1%2C96&et\\_pb\\_include\\_posts=yes](https://guidelines.aimspecialtyhealth.com/?s=patency+capsule&et_pb_searchform_submit=et_search_process&et_pb_search_cat=11%2C1%2C96&et_pb_include_posts=yes)

AGILE™ Patency System (Given Imaging Ltd.) For Verification Of Gastrointestinal Patency Prior To Capsule Endoscopy - ARCHIVED Mar 20, 2010. (n.d.). Retrieved Dec 1, 2022, from HAYES:  
<https://evidence.hayesinc.com/report/htb.agile>

CFR - Code of Federal Regulations Title 21 876.1300 Ingestible telemetric gastrointestinal capsule imaging system. (2022, Jul 20). Retrieved Dec 1, 2022, from FDA:  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=876.1300>

Guideline: The role of endoscopy in inflammatory bowel disease. (2015). Retrieved Dec 1, 2022, from American Society for Gastrointestinal Endoscopy (ASGE): [https://www.asge.org/docs/default-source/education/practice\\_guidelines/doc-endoscopy\\_in\\_ibd.pdf?sfvrsn=87c94951\\_6](https://www.asge.org/docs/default-source/education/practice_guidelines/doc-endoscopy_in_ibd.pdf?sfvrsn=87c94951_6)

Local Coverage Determination (LCD) Colon Capsule Endoscopy (CCE) L38755. (2021, Feb 25). Retrieved Dec 1, 2022, from Centers for Medicare and Medicaid Services: <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=38755&ver=6>

PillCam Patency Capsule. (2022). Retrieved Dec 1, 2022, from Medtronic: <https://www.medtronic.com/covidien/en-gb/products/capsule-endoscopy/pillcam-capsules/pillcam-patency-capsule.html#>

Procedure Fee Files & CPT Codes. (2022). Retrieved Dec 1, 2022, from Department of Medical Assistance Services: <https://www.dmas.virginia.gov/for-providers/rates-and-rate-setting/procedure-fee-files-cpt-codes/>

Technology Status Evaluation Report: Video capsule endoscopy. (2021). Retrieved Dec 1, 2022, from American Society for Gastrointestinal Endoscopy: [https://www.asge.org/docs/default-source/default-document-library/piis0016510720350227.pdf?sfvrsn=9684f15d\\_0](https://www.asge.org/docs/default-source/default-document-library/piis0016510720350227.pdf?sfvrsn=9684f15d_0)

Use of a Patency Capsule to Verify Small Bowel Patency Prior to Capsule Endoscopy - ARCHIVED Jun 17, 2022. (n.d.). Retrieved Dec 1, 2022, from HAYES 2: <https://evidence.hayesinc.com/report/earb.patency5164>

Wireless video capsule endoscopy. (2022, Apr 18). Retrieved Dec 1, 2022, from UpToDate: [https://www.uptodate.com/contents/wireless-video-capsule-endoscopy?search=agile&source=search\\_result&selectedTitle=4~4&usage\\_type=default&display\\_rank=4](https://www.uptodate.com/contents/wireless-video-capsule-endoscopy?search=agile&source=search_result&selectedTitle=4~4&usage_type=default&display_rank=4)

### 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 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.*

### Keywords:

SHP Agile Patency System, SHP Medical 81, endoscopy, smartpill, chromoendoscopy, swallow, device, capsule endoscopy, small intestine, digestive tract, Chrohns, inflammatory bowel disease, SHP Medical 131, patency capsule test, Ingestible gastrointestinal capsule, Biodegradable Capsule with a Radiofrequency Identification Tag