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SHP Agile Patency System

AUTH: SHP Medical 131 v4 (AC)

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Coverage

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See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.

Application to Products

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Policy is applicable to all products.

Authorization Requirements

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Pre-certification by the Plan is required.

Description of Item or Service

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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.

Exceptions and Limitations

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There is insufficient scientific evidence to support the medical necessity of this service as it is not shown to improve health outcomes upon technology review.

Clinical Indications for Procedure

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- NA

Document History

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- 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

Coding Information

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- CPT/HCPCS codes covered if policy criteria is met:
 - None
- CPT/HCPCS codes considered not medically necessary per this Policy:
 - 91299 - Unlisted diagnostic gastroenterology procedure

References

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References used include but are not limited to the following:

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

(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

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

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

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

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