

# **VARIBAR<sup>®</sup> (barium sulfate)**

# REIMBURSEMENT RESOURCE KIT

March 2021

## **DISCLAIMERS**

The information provided here is general reimbursement information for VARIBAR<sup>®</sup> (barium sulfate). It is not legal advice, nor is it advice about how to code, complete, or submit any particular claim for payment. Although we supply this information based on our current knowledge, it is always the provider's responsibility to determine and submit appropriate codes, charges, modifiers, and bills for the services that were rendered. This coding and reimbursement information is subject to change without notice. Payers or their local branches may have their own coding and reimbursement requirements and policies. Before filing any claims, providers should verify current requirements and policies with the payer.

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# CONTENTS

<b>Product Indications</b> .....	3
<b>Coding Nomenclature</b> .....	4
<b>Coding Information</b> .....	5
<b>2021 Medicare National Average Payment Rates</b> .....	6
<b>Quality Payment Program and MIPS (Merit-Based Incentive Payment System)</b> .....	7-8
<b>Quality Measure 182: Functional Outcome Assessment</b> .....	9-10
<b>Hospital Quality Measures and Readmission Program – Pneumonia</b> .....	11
<b>Example of Hospital Billing</b> .....	12
<b>Example of Billing for Independent Diagnostics Testing Facility</b> .....	13
<b>Billing and Submitting Charges</b> .....	14
<b>Ordering Information</b> .....	15
<b>Reimbursement Hotline</b> .....	16
<b>References</b> .....	17

**The ONLY Contrast Validated** for Standardized, Well-Tested Protocols  
During Modified Barium Swallow Studies (MBSS)<sup>1</sup>



### The POWER of Consistency in MBSS

Developing standards for the MBSS is a key concern throughout the Speech/Language Pathology (SLP) community.<sup>1,2</sup> The VARIBAR® products were developed in cooperation with SLPs to help standardize diagnostic materials for accurate comparisons between studies.

**The ONLY Premixed\*, Premeasured, and Precise** Barium Preparations for MBSS that may:

- Enable reproducible results<sup>2-5</sup>
- Support high-quality imaging<sup>2,3</sup>
- Reduce preparation time and wasted materials
- Avoid undesirable coating inherent to traditional GI barium sulfate preparations<sup>2,4,5</sup>

\*VARIBAR® THIN LIQUID (barium sulfate) for oral suspension is supplied as a powder and reconstituted to a standard volume with water. All images shown are representative images from referenced studies. Individual results may vary.

#### INDICATIONS AND USAGE:

VARIBAR® THIN HONEY (barium sulfate) oral suspension, VARIBAR® NECTAR (barium sulfate) oral suspension, and VARIBAR® THIN LIQUID (barium sulfate) for oral suspension, are indicated for use in modified barium swallow examinations to evaluate the oral and pharyngeal function and morphology in adult and pediatric patients. VARIBAR® HONEY (barium sulfate) oral suspension and VARIBAR® PUDDING (barium sulfate) oral paste are indicated for use in modified barium swallow examinations to evaluate the oral and pharyngeal function and morphology in adult and pediatric patients 6 months of age and older.

#### IMPORTANT SAFETY INFORMATION:

For Oral Administration. This product should not be used in patients with known or suspected perforation of the GI tract, known obstruction of the GI tract, high risk of aspiration, or hypersensitivity to barium sulfate products. Rarely, severe allergic reactions of anaphylactoid nature have been reported following administration of barium sulfate contrast agents. Aspiration may occur during the modified barium swallow examination, monitor the patient for aspiration.

Please see full Prescribing Information for VARIBAR products at: <https://imaging.bracco.com/us-en/products/fluoroscopy/varibar>

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit <https://www.fda.gov/medwatch> or call 1-800-FDA-1088.

## **CPT® (Current Procedural Terminology)**

Codes used to report the service or procedure performed.

## **Technical Component Payment (TC)**

The Technical Component reflects the technical portion of the radiology, laboratory, medical, or surgical procedure code. When the technical component is provided by a health care provider other than the physician providing the professional component, the health care provider bills for the technical component by adding Modifier –TC to the applicable code. The TC rate is payment for the facility's cost of rent, equipment, utilities, supplies, administrative and technical salaries and benefits, and all other overhead expenses.

## **Professional Component (26)**

The professional component of a charge covers the cost of the physician's professional services and interpretation only.

## **Global (G)**

A Global Payment is the sum of both the Technical Component (TC) and Professional Component (26).

## **HCPCS (Healthcare Common Procedure Coding System)**

Codes used to report the provision of supplies, materials, injections, and certain services and procedures. The VARIBAR® (barium sulfate) is considered a drug used as a supply, and it can be coded under revenue code 0255, 0270, or 0621.

## **ICD-10-CM (International Classification of Disease)**

Codes used to describe a patient's signs and symptoms that would represent a medically necessary reason for performing the procedure. ICD-10 codes need to be entered on the claim form. ICD-10-CM is the 10<sup>th</sup> revision of the International Statistical Classification of Diseases and Related Health Problems (ICD), a medical classification list by the World Health Organization (WHO).

## **APC (Ambulatory Payment Classification)**

In most cases, the unit of payment under the Hospital Outpatient Prospective Payment System (HOPPS) is the APC. CMS assigns individual services HCPCS & CPT codes to APCs based on similar clinical characteristics and similar costs. The payment rate and copayment calculated for an APC apply to each service within the APC.

## **NDC (National Drug Code)**

An NDC code provides a unique identifier for a specific drug and dose. The NDCs for VARIBAR® contrast can be found on page 14.

## **Medicare Addendum B**

These files are updated quarterly and reflect HOPPS payment rates for HCPCS codes and APC codes. This can be found at: <https://www.cms.gov/Medicare/Medicare-Fee-For-Service-Payment/HospitalOutpatientpps/Addendum-A-and-Addendum-B-Updates>.

## **Medicare Physician Fee Schedule (MPFS)**

Find out physician payment for specific geographic locations in the country for different procedures. This schedule provides: global (G), technical (TC), and professional (26) component payment rates. To find out more information on specific locations visit: <https://www.cms.gov/apps/physician-fee-schedule/overview.aspx>.

**HCPCS Code:** There is no HCPCS code for any type of barium product, including VARIBAR® (barium sulfate). It may be coded under one of the Revenue Codes listed below.

## Procedure (CPT) Codes<sup>6</sup>

CPT Code	Description
<b>74230</b>	Radiologic examination, swallowing function, with cineradiography/videoradiography, including scout neck radiograph(s) and delayed image(s), when performed, contrast (eg, barium) study
<b>92611</b>	Motion fluoroscopic evaluation of swallowing function by cine or video recording

Both **74230** and **92611** must be coded together. **74230** represents the radiologist's work and **92611** represents the work of the Speech Language Pathologist.

## Revenue Codes<sup>7</sup>

For the Barium Products Used During Procedure:	Description
<b>0255</b>	Drugs incident to radiology
<b>0270</b>	Medical/surgical supplies – general
<b>0621</b>	Medical/surgical supplies – extension of 027X- incident to radiology

For the Modified Barium Swallow Study Procedure:	Description
<b>0320</b>	Radiology Diagnostic - General
<b>0444</b>	Speech Therapy Language Pathology – Evaluation or reevaluation

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Hospital Outpatient Prospective Payment System <sup>8</sup>		
74230	Global (G)	\$178.55
Independent Diagnostic Imaging Centers <sup>9</sup>		
74230	Global (G)	\$136.43
74230	Technical Component (TC)	\$109.91
74230	Professional Component (26)	\$26.52
92611	Speech Language Pathology	\$93.86

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# QUALITY PAYMENT PROGRAM AND MIPS (MERIT-BASED INCENTIVE PAYMENT SYSTEM)

## Quality Payment Program and MIPS (Merit-Based Incentive Payment System) for Speech Language Pathologists<sup>10</sup>



### What?

**CMS is required by law to implement a quality payment incentive program, referred to as the Quality Payment Program, which rewards value and outcomes in one of two ways: Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs).**

Under MIPS, clinicians are included if they are an eligible clinician type and meet the low volume threshold, which is based on allowed charges for covered professional services under the Medicare Physician Fee Schedule (PFS) and the number of Medicare Part B patients who are furnished covered professional services under the Medicare Physician Fee Schedule.

Performance is measured through the data clinicians report in four areas - Quality, Improvement Activities, Promoting Interoperability, and Cost.

### How it Works

There are four performance categories that make up the final score. The final score determines what the payment adjustment will be. These four categories are:



#### Quality:

This category covers the quality of care delivered, based on performance measures created by CMS, as well as medical professional and stakeholder groups.



#### Promoting Interoperability (PI):

This is done by proactively sharing information with other clinicians or the patient in a comprehensive manner and using standardized protocols and materials to share clinical data that are unambiguous and measurable. This may include: sharing test results, visit summaries, and therapeutic plans with the patient and other facilities to coordinate care.



#### Improvement Activities:

This is a performance category that includes an inventory of activities that assess how the care processes improves, enhance patient engagement in care, and increase access to care. The inventory allows activities to be chosen appropriate to the practice from categories such as, enhancing care coordination, patient and clinician shared decision-making, and expansion of practice access.



#### Cost:

MIPS uses cost measures to gauge the total cost of care during the year or during a hospital stay.

### Why?

MIPS was designed to tie payments to quality and cost-efficient care, drive improvement in care processes and health outcomes, increase the use of healthcare information, and reduce the cost of care.

### When?

The MIPS Performance Year begins on January 1 and ends on December 31 each year. Program participants must report data collected during one calendar year by March 31 of the following calendar year.

**Speech Language Pathologists (SLPs) who treat Medicare Part B Patients may be required to participate in MIPS. One of the key measures that impact Dysphagia is Measure 182.**

## **Measure 182:**

Functional Outcome Assessment evaluates a current functional outcome assessment utilizing a standardized tool and a care plan if indicated within the previous 30 days.

In order to meet the requirement of this measure, selecting evidence-based protocols and proven products is key:

- VARIBAR products are the only FDA-approved products indicated for Modified Barium Swallow Studies (MBSS)<sup>11</sup>. The VARIBAR line, with standardized viscosities, helps to eliminate the unpredictability of varied homemade barium preparations.
- VARIBAR products are the only contrast agents validated for standardized, well-tested protocols during Modified Barium Swallow Studies<sup>1,3</sup>
- The Modified Barium Swallow Impairment Profile (MBSImP™ ©) Tool is a Validated Protocol that standardizes barium dosages used in Modified Barium Swallow Studies. For more information on the MBSImP, please visit:  
<https://www.northernspeech.com/mbsimp/>

## **Why is CMS putting forward these measures?**

In the Quality Measure Document #182– The Centers for Medicare and Medicaid Services (CMS) states the following:

**RATIONALE:** Standardized outcome assessments, questionnaires or tools are a vital part of evidence-based practice. Despite the recognition of the importance of outcomes assessments, questionnaires and tools, recent evidence suggests their use in clinical practice is limited. Utilization of the appropriate outcomes assessment, questionnaires, and tools enhances clinical practice by:

- identifying and quantifying body function and structure limitations,
- formulating evaluation, diagnosis, and prognosis,
- forming the plan of care,
- assisting in evaluating the patient progress towards the goals and validating the benefits of treatment,
- improving communication between client, clinician, and third party payer,
- assisting to improve the documentation of care provided (Leshner, et al., 2016; Potter, et al., 2011; Schenk, et al. 2016). <https://qpp.cms.gov/mips/explore-measures/quality-measures?py=2020&specialtyMeasureSet=Speech%20Language%20Pathology>

**For more information on MACRA and MIPS visit the CMS official website and the ASHA website:**

**QPP** - <https://qpp.cms.gov/mips/quality-measures>

**ASHA** - <https://www.asha.org/practice/reimbursement/medicare/mips-quality-measures-for-speech-language-pathologists/>

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# QUALITY MEASURE 182: FUNCTIONAL OUTCOME ASSESSMENT

## Key Terms to Know

**Standardized Tool:** A tool that has been normed and validated. Examples of tools for functional outcome assessment include, but are not limited to: Oswestry Disability Index (ODI), Roland Morris Disability/Activity Questionnaire (RM), Neck Disability Index (NDI), Patient-Reported Outcomes Measurement Information System (PROMIS), Disabilities of the Arm, Shoulder and Hand (DASH), Western Ontario and McMaster University Osteoarthritis Index Physical Function subscale (WOMAC-PF), Dynamic Imaging Grade of Swallowing Toxicity (DIGEST™) by MD Anderson, and the Modified Barium Swallow Impairment Profile (MBSImP™ ©)

**Functional Outcome Assessment:** Patient completed questionnaires designed to measure a patient's limitations in performing the usual human tasks of living and to directly quantify functional and behavioral symptoms.

**Current (Functional Outcome Assessment):** A patient having a documented functional outcome assessment utilizing a standardized tool and a care plan if indicated within the previous 30 days.

**Functional Outcome Deficiencies:** Impairment or loss of function related to musculoskeletal/neuromusculoskeletal capacity. Examples include but are not limited to: restricted flexion, extension and rotation, back pain, neck pain, pain in the joints of the arms or legs, and headaches.

**Care Plan:** A care plan is an ordered assembly of expected/planned activities or actionable elements based on identified deficiencies. These may include observations, goals, services, appointments, and procedures, usually organized in phases or sessions, which have the objective of organizing and managing health care activity for the patient, often focused on one or more of the patient's health care problems. Care plans may also be known as a treatment plan.

**Not Eligible (Denominator Exception):** A patient is not eligible if one or more of the following reason(s) is documented at the time of the encounter:

- Patient refuses to participate
- Patient unable to complete questionnaire
- Patient is in an urgent or emergent situation where time is of the essence and to delay treatment would jeopardize the patient's health status

# QUALITY MEASURE 182: FUNCTIONAL OUTCOME ASSESSMENT

## Quality Measure 182: Functional Outcome Assessment Codes<sup>10</sup>

<b>Reporting Criteria</b>	Percentage of visits for patients 18 years and older, documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter, AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies. It must be reported at every visit to which it applies during the 2020 reporting period.
<b>CPT Codes</b>	92610, 92611, 92613
<b>Quality Data Codes (QDCs)</b> <b>Pick one QDC to report on the same claim as the applicable CPT code.</b>	
<b>G8539 Performance met</b>	Functional outcome assessment documented as positive using a standardized tool AND a care plan, based on identified deficiencies on the date of the functional outcome assessment, is documented
<b>G8542 Performance met</b>	Functional outcome assessment using a standardized tool is documented; no functional deficiencies identified, care plan not required
<b>G8942 Performance met</b>	Functional outcome assessment using a standardized tool is documented within the previous 30 days and a care plan, based on identified deficiencies on the date of the functional outcome assessment, is documented
<b>G8540 Denominator exception</b>	Functional outcome assessment not documented as being performed, documentation the patient is not eligible for a functional outcome assessment using a standardized tool at the time of the encounter
<b>G9227 Denominator exception</b>	Functional outcome assessment documented, care plan not documented, documentation of the patient is not eligible for a care plan at the time of the encounter
<b>G8541 Performance not met</b>	Functional outcome assessment using a standardized tool not documented, reason not given
<b>G8543 Performance not met</b>	Documentation of a positive functional outcome assessment using a standardized tool; care plan not documented, reason not given

# HOSPITAL QUALITY MEASURES AND READMISSION PROGRAM – PNEUMONIA

CMIT REFERENCE	MEASURE TITLE	NQF ID
<b>83</b>	Pneumonia (PN) 30-Day Readmission Rate	<b>0506</b>
<b>92</b>	Hospital 30-Day, All-Cause, Risk Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization	<b>468</b>
<b>2852</b>	PN Excess Days in Acute Care (EDAC)	<b>2882</b>
<b>2277</b>	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Pneumonia	<b>2579</b>

[https://cmit.cms.gov/CMIT\\_public/ViewMeasureSummary](https://cmit.cms.gov/CMIT_public/ViewMeasureSummary)

**Sample hospital setting billing form UB-04 CMS-1450**  
**Modified Barium Swallow Study (MBSS)**

Note: A JW Modifier is not needed as these products are not single dose and not separately payable by Medicare.

# EXAMPLE OF INDEPENDENT DIAGNOSTIC TESTING FACILITY (IDTF) BILLING

Sample physician billing global non-hospital outpatient setting CMS-1500

Modified Barium Swallow Study (MBSS)



## HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

<input type="checkbox"/> PICA										<input type="checkbox"/>									
1. MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA BLK LUNG <input type="checkbox"/> OTHER <input type="checkbox"/> (Medicare#) (Medicaid#) (ID#/DoD#) (Member ID#) (ID#)										1a. INSURED'S I.D. NUMBER (For Program in Item 1)									
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)										3. PATIENT'S BIRTH DATE MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>									
5. PATIENT'S ADDRESS (No., Street)										6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>									
CITY STATE										7. INSURED'S ADDRESS (No., Street)									
ZIP CODE TELEPHONE (Includes Area Code)										CITY STATE									
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)										10. IS PATIENT'S CONDITION RELATED TO:									
a. OTHER INSURED'S POLICY OR GROUP NUMBER										a. EMPLOYMENT? (Current or Previous) YES <input type="checkbox"/> NO <input type="checkbox"/>									
b. RESERVED FOR NUCC USE										b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State)									
Form Locator 19 & 24D: Global Billing Example										11. INSURED'S POLICY GROUP OR FECA NUMBER									
F-19 – In order to facilitate coverage and payment, provide a description of the contrast drug (See Medicare contractors or private payer instructions for information required)										a. INSURED'S DATE OF BIRTH MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>									
F-24D – Enter CPT® or HCPCS Code for procedures performed and interpreted by physician										b. OTHER CLAIM ID (Designated by NUCC)									
Form Locator 24G: Enter the number of units based on the CPT® or HCPCS Code description										c. INSURANCE PLAN NAME OR PROGRAM NAME									
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE										13. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES <input type="checkbox"/> NO <input type="checkbox"/> If yes, complete items 9, 9a, and 9d.									
19. ADDITIONAL CLAIM INFORMATION (Designate)										13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.									
VARIBAR® (barium sulfate)										SIGNED									
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)										16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY									
A. B. C. D. E. F. G. H. I. J. K. L.										18. H. I. J. K. L.									
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY B. PLACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER E. DIAGNOSIS POINTER										F. G. DAYS OR UNITS H. EPSDT Family Plan I. ID. QUAL. J. RENDERING PROVIDER ID. #									
1 04 25 21 04 25 21 92611										XXXX XX 1 NPI									
2 04 25 21 04 25 21 74230										XXX XX 1 NPI									
3										NPI									
4										NPI									
5										NPI									
6										NPI									
25. FEDERAL TAX I.D. NUMBER SSN EIN										26. PATIENT'S ACCOUNT NO.									
27. ACCEPT ASSIGNMENT? YES <input type="checkbox"/> NO <input type="checkbox"/>										28. TOTAL CHARGE \$									
29. AMOUNT PAID \$										30. Rsvd for NUCC Use									
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)										32. SERVICE FACILITY LOCATION INFORMATION									
SIGNED DATE										33. BILLING PROVIDER INFO & PH # ( )									

Bracco Diagnostics Inc. cannot guarantee coverage or payment for products or procedures at any particular level. For more specific information please contact your Medicare contractor or the patient's insurer.

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-1

Committed to Science,  
Committed to You.™



## Checks to Success

The provider has included the...

- ✓ CPT procedure code
- ✓ Proper service units
- ✓ Contrast drugs included with either NDC number or HCPCS code
- ✓ Principal diagnostic code (and secondary if applicable)
- ✓ Applicable revenue codes (hospital only)
- ✓ Documentation providing the medical necessity for all codes billed



Properly submitted bills and charges are used in creating Medicare Fee Schedules. Ensuring that all aspects of the procedure are accounted for is necessary to support appropriate payment rates in the future.

All barium products are ordered through distributors.

PRODUCT	NDC NUMBER	DESCRIPTION
VARIBAR® THIN LIQUID (barium sulfate) for oral suspension*	032909-105-10	148 g (24 per case)
VARIBAR® NECTAR (barium sulfate) oral suspension	032909-116-00	240 mL (12 per case)
VARIBAR® THIN HONEY (barium sulfate) oral suspension	032909-121-07	250 mL (12 per case)
VARIBAR® HONEY (barium sulfate) oral suspension	032909-122-07	250 mL (12 per case)
VARIBAR® PUDDING (barium sulfate) oral paste	032909-125-22	230 mL (12 per case)

\*VARIBAR® THIN LIQUID (barium sulfate) for oral suspension is supplied in a powder and constituted to a standard volume with water.

## Questions?

Call Bracco Customer Service at  
**1-877-BRACCO-9 (1-877-272-2269), Option 2.**

To contact a VARIBAR® (barium sulfate) representative, please contact  
**VARIBAR@diag.bracco.com**

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# REIMBURSEMENT HOTLINE

## How we support you

The Bracco Reimbursement Hotline is here to support you for all your reimbursement needs.

Ask coding and billing questions regarding Bracco Diagnostics products and procedures related to those products.

- ✓ HCPCS codes for products
- ✓ CPT® and HCPCS codes for procedures
- ✓ Medicare payments
- ✓ Monday-Friday: 9:00 AM-6:00 PM Eastern Time

For more information on reimbursement, contact the Bracco Reimbursement Hotline at:



**1-800-349-1388**

[Askbracco@reimbursement.bracco.com](mailto:Askbracco@reimbursement.bracco.com)

## Receive Bi-monthly Reimbursement/Compliance Question & Answers

### Access a Q&A Searchable Database:

- ✓ Search by topics and gain access to the archived Q&A
- ✓ Reach the hotline from the webpage
- ✓ Organized by Radiology, Nuclear Medicine, Ultrasound, Cardiology and Documentation

**Sign up to automatically receive our Q&As**

**To get the most benefit from this service as a Bracco customer, we encourage you to:**

- ✓ Bookmark the Q&A webpage to search for topics of interest Q&A on specific topics
- ✓ Sign up and receive the Q&A every two weeks

Go to the Q&A webpage below at:  
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## INDICATIONS AND USAGE:

VARIBAR® THIN HONEY (barium sulfate) oral suspension, VARIBAR® NECTAR (barium sulfate) oral suspension, and VARIBAR® THIN LIQUID (barium sulfate) for oral suspension, are indicated for use in modified barium swallow examinations to evaluate the oral and pharyngeal function and morphology in adult and pediatric patients. VARIBAR® HONEY (barium sulfate) oral suspension and VARIBAR® PUDDING (barium sulfate) oral paste are indicated for use in modified barium swallow examinations to evaluate the oral and pharyngeal function and morphology in adult and pediatric patients 6 months of age and older.

## IMPORTANT SAFETY INFORMATION:

For Oral Administration. This product should not be used in patients with known or suspected perforation of the GI tract, known obstruction of the GI tract, high risk of aspiration, or hypersensitivity to barium sulfate products. Rarely, severe allergic reactions of anaphylactoid nature have been reported following administration of barium sulfate contrast agents. Aspiration may occur during the modified barium swallow examination, monitor the patient for aspiration.

Please see full Prescribing Information for VARIBAR products at: <https://imaging.bracco.com/us-en/products/fluoroscopy/varibar>

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit <https://www.fda.gov/medwatch> or call 1-800-FDA-1088.

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