



Reimbursement support is available at: <a href="mailto:methapharm@thepinnaclehealthgroup.com">methapharm@thepinnaclehealthgroup.com</a> or 866-369-9290

# THE MANNITOL CHALLENGE TEST WITH ARIDOL

Aridol (the Mannitol Challenge Test) is used to assess patients experiencing respiratory symptoms and suspected of having asthma or exercise-induced bronchoconstriction (EIB).

- One ARIDOL test kit is for single patient use and contains dry powder mannitol capsules in graduated doses (0 mg, 5 mg, 10 mg, 20 mg, and 40 mg) and an inhaler necessary to perform one challenge test (please see next page for Mannitol Challenge Test Dosing Schedule).
- Capsule contents are to be inhaled in increasing doses until either a positive response (15% reduction in FEV<sub>1</sub> from baseline or a 10% incremental reduction in FEV<sub>1</sub> between consecutive doses) is achieved OR all capsules are inhaled. The maximum total dose administered is 635 mg.

Reimbursement for the mannitol challenge test, as well as the use of modifiers to report discarded amounts of mannitol, will vary in the hospital outpatient setting compared with the physician office setting. Regardless, each billed unit represents 5 mg of mannitol, for a total of 127 billable units.

#### 1. HOSPITAL OUTPATIENT CODING AND REIMBURSEMENT

In the hospital outpatient prospective payment system, CMS assigns all CPT and HCPCS codes a status indicator (SI) which indicates if and how a service is considered for payment. The status indicators that apply to the CPT and HCPCS codes listed in this guide and their definitions are provided below:

N Payment packaged with the primary procedure

**N/A** Payment not applicable in this setting

Significant procedure; separate payment made; multiple procedure discount does not apply

CPT/HCPCS	Descriptor	OPPS		Physician
		SI	Payment	Payment
Aridol				
J7665	Mannitol, administered through an inhaler, per 5 mg	N	Packaged	N/A
<b>Bronchial Tests</b>				
94070	Bronchospasm provocation evaluation, multiple spirometric determinations as in 94010, with administered agents (e.g., antigen[s], cold air, methacholine)	S	\$299	\$27
95070	Inhalation bronchial challenge testing (not including necessary pulmonary function tests), with histamine, methacholine, or similar compounds	S	\$511	N/A

### **Billing Examples in Hospital Outpatient Setting:**

For each mannitol challenge test, 127 units of J7665 are billed regardless of test outcome.

**Example 1:** If the Mannitol Challenge is stopped at Step 6, you would bill a total of 635 mg as follows:

127 units of J7665

**Example 2:** If the Mannitol Challenge continues until Step 9, where all doses are delivered, you would bill a total of 635 mg as follows:

127 units of J7665

Please note that payment for Aridol (mannitol) is packaged in the hospital outpatient setting (i.e., not paid separately) and use of the -JW and -JZ modifiers is therefore not necessary.



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### 2. PHYSICIAN OFFICE CODING AND REIMBURSEMENT

CPT/HCPCS	Descriptor			
Aridol		Payment		
J7665	Mannitol, administered through an inhaler, per 5 mg	Contractor Priced*		
Bronchial Tests				
94070	Bronchospasm provocation evaluation, multiple spirometric determinations as in 94010, with administered agents (e.g., antigen[s], cold air, methacholine)			
95070	Inhalation bronchial challenge testing (not including necessary pulmonary function tests), with histamine, methacholine, or similar compounds	\$34		

<sup>\*</sup>Medicare reimbursement is based on WAC or Invoice. Claims billed with J7665 should indicate the invoice amount in Box 19 (Narrative Field) on the CMS 1500 form.

#### Use of Modifiers -JW and -JZ

Modifier	Descriptor
JW	Amount discarded/not administered
JZ	Zero drug amount discarded/not administered to any patient

Providers and suppliers are required to report the -JW modifier on Part B drug claims for all separately payable discarded drugs and biologicals. The amount discarded should be billed on a separate line with the JW modifier. The unit field (HCFA 1500: box 24, column G) should reflect the amount of drug discarded.

Providers and suppliers are required to report the JZ modifier on all claims that bill for drugs from single-dose containers that are separately payable under Medicare Part B when there are no discarded amounts. For additional information, please refer to the following resource:

Discarded Drugs and Biologicals — JW Modifier and JZ Modifier Policy Frequently Asked Questions.

#### **Billing Examples for Physician Office Setting:**

For each mannitol challenge test, a total of 127 units of J7665 are billed.

Example #1: Use of Modifier -JW If the Mannitol Challenge is stopped at Step 6, you bill a total of 635 mg as follows:

31 units of J7665; and 96 units of J7665-JW

Example #2: Use of Modifier -JZ If the Mannitol Challenge is stopped at Step 9, where all doses are delivered, you would bill a total of 635 mg as follows:

127 units of J7665-JZ

#### **Mannitol Challenge Test Dosing Schedule**

The Mannitol Challenge dosing schedule is the same for all patients. The following chart indicates the number of units to bill for each "Step" of the challenge for patients seen in the Physician Office setting. The test is stopped at the "Step" at which the patient meets the test criteria, and the corresponding units of J7665, J7665-JZ, and J7665-JW should be reported by the provider. Please note that -JW and -JZ codes are only reported for patients seen in Physician Office setting.

			TOTAL UNITS REPORTED		
	Units per Step	Dose per Step	J7665	J7665-JZ	J7665-JW
Step 1	0	0 mg	0	0	127
Step 2	1	5 mg	1	0	126
Step 3	2	10 mg	3	0	124
Step 4	4	20 mg	7	0	120
Step 5	8	40 mg	15	0	112
Step 6	16	80 mg	31	0	96
Step 7	32	160 mg	63	0	64
Step 8	32	160 mg	95	0	32
Step 9	32	160 mg	N/A	127	N/A



# IMPORTANT SAFETY INFORMATION

#### WARNING: RISK OF SEVERE BRONCHOSPASM

Mannitol, the active ingredient in ARIDOL, acts as a bronchoconstrictor and may cause severe bronchospasm. Bronchial challenge testing with ARIDOL is for diagnostic purposes only. Bronchial challenge testing with ARIDOL should only be conducted by trained professionals under the supervision of a physician familiar with all aspects of the bronchial challenge test and the management of acute bronchospasm. Medications (such as short-acting inhaled beta-agonist) and equipment to treat severe bronchospasm must be present in the testing area. If severe bronchospasm occurs it should be treated immediately by administration of a short-acting inhaled beta-agonist. Because of the potential for severe bronchoconstriction, the bronchial challenge testing with ARIDOL should not be performed in any patient with clinically apparent asthma or very low baseline pulmonary function tests (e.g., FEV<sub>1</sub> <1-1.5 liters or <70% of the predicted values) [see Warnings and Precautions (5.1) of the Prescribing Information].

Mannitol, the active ingredient in ARIDOL, acts as a bronchoconstrictor and may cause severe bronchospasm in susceptible patients. The test should only be conducted by trained professionals under the supervision of a physician familiar with all aspects of the bronchial challenge test and the management of acute bronchospasm. Patients should not be left unattended during the bronchial challenge test. Medications and equipment to treat severe bronchospasm must be present in the testing area.

If a patient has a ≥10% reduction in FEV₁ (from pre-challenge FEV₁) on administration of the 0 mg capsule, the ARIDOL Bronchial Challenge Test should be discontinued, and the patient should be given a dose of a short-acting inhaled beta-agonist and monitored accordingly. Patients with either a positive response to bronchial challenge testing with ARIDOL or significant respiratory symptoms should receive a short-acting inhaled beta-agonist. Patients should be monitored until fully recovered to within baseline.

ARIDOL is contraindicated in patients with known hypersensitivity to mannitol or to the gelatin used to make the capsules and patients with conditions that may be compromised by induced bronchospasm or repeated spirometry maneuvers. Some examples include aortic or cerebral aneurysm, uncontrolled hypertension, recent myocardial infarction or cerebral vascular accident [see Warnings and Precautions (5.2) of the Prescribing Information].

Please see complete prescribing information available for download at www.aridolchallenge.com or on request by calling Methapharm Medical Information at 1-866-701-4636. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA (332)-1088. This information is provided as a professional courtesy, and it is intended to provide data available to us that may assist you in deriving your own conclusions and opinions. This information is not intended to advocate any indications, dosage, or other claim that is not described in the package insert.

## **DISCLAIMER**

The coding and reimbursement information provided is for educational purposes and does not assure coverage of the specific item or service in any given case. Information provided as part of this document is not intended to provide legal, patient specific coding or claims submission information and based upon the current landscape utilizing the information that is currently available.

Procedure coding should be based upon medical necessity. Methapharm and The Pinnacle Health Group make no guarantee of coverage or reimbursement of fees. All payment rates provided are the Medicare national average and subject to change. Contact your local Medicare Administrator Contractor (MAC) or CMS geographic adjusted rates. To the extent that you submit cost information to Medicare, Medicaid or any other reimbursement program to support claims for services or items, you are obligated to accurately report the actual price paid for such items, including any subsequent adjustments. Current Procedural Terminology numeric codes, descriptions, and modifiers are trademarks and copyrights of the AMA.

## REFERENCES

- CY 2024 Hospital Outpatient Prospective Payment and Ambulatory Payment Systems Final Rule (CMS-1786-FC); Addendum B and ASC Addenda.
- CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; (CMS-1784-F); Addendum B.
   All MPFS Fee Schedules calculated using CF of \$32.7442 effective January 1, 2024. Please note, payments rates may be subject to change pending legislation (H.R.6683 Preserving Seniors' Access to Physicians Act of 2023).
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