Omnipaque™ (iohexol) Injection

Omnipaque is a nonionic, iodinated, low osmolar contrast media (LOCM). Omnipaque’s indications include a broad range of intrathecal, intravascular, and oral/body cavity diagnostic procedures.

Coding and Payment Information

Under HOPPS, Medicare will continue “packaging” payment for contrast imaging agents into the payment for the associated procedure.

Contrast media is separately payable in physician offices and freestanding imaging centers. Payment is based on the average sales price (ASP) + 6%. ASP rates are adjusted quarterly and are based on the prior quarter’s ASP data. The rates can be viewed on the Centers for Medicare & Medicaid Services (CMS) web site at:

http://www.cms.gov/McrPartBDrugAvgSalesPrice/

<table>
<thead>
<tr>
<th>CPT®/HCPCS Code</th>
<th>Description</th>
<th>Hospital Outpatient Department</th>
<th>Physician Offices and Freestanding Imaging Centers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q9965</td>
<td>Low osmolar contrast material, 100-199 mg/ml iodine concentration, per ml</td>
<td>Packaged</td>
<td>ASP + 6%</td>
</tr>
<tr>
<td>Q9966</td>
<td>Low osmolar contrast material, 200-299 mg/ml iodine concentration, per ml</td>
<td>Packaged</td>
<td>ASP + 6%</td>
</tr>
<tr>
<td>Q9967</td>
<td>Low osmolar contrast material, 300-399 mg/ml iodine concentration, per ml</td>
<td>Packaged</td>
<td>ASP + 6%</td>
</tr>
</tbody>
</table>

Private insurer and Medicaid payment rates may vary and different codes may be required.
Important Risk and Safety Information about Omnipaque (iohexol) Injection

Omnipaque 140 mgI/mL and 350 mgI/mL - NOT FOR INTRATHECAL USE

SEVERE ADVERSE EVENTS—INADVERTENT INTRATHECAL ADMINISTRATION -

Serious adverse reactions have been reported due to the inadvertent intrathecal administration of iodinated contrast media that are not indicated for intrathecal use. These reactions include: death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema. Special attention must be given to insure that Omnipaque 140 and 350 are not administered intrathecally.

INDICATIONS - Intravascular - Adults: Omnipaque 350 is indicated for angiocardiography (ventriculography, selective coronary arteriography), aortography, including studies of the aortic root, aortic arch, ascending aorta, abdominal aorta and its branches, contrast enhancement for computed tomographic (CT) head and body imaging, intravenous (IV) digital subtraction angiography (DSA) of the head, neck, abdominal, renal and peripheral vessels, peripheral arteriography, and excretory urography. Omnipaque 300 is indicated in adults for aortography including studies of the aortic arch, abdominal aorta and its branches, contrast enhancement for CT head and body imaging, cerebral arteriography, phlebography, and excretory urography. Omnipaque 240 is indicated for contrast enhancement for CT head imaging and phlebography. Omnipaque 140 is indicated intra-arterial DSA of the head, neck, abdominal, renal and peripheral vessels. Children: Omnipaque 350 is indicated for angiocardiography (ventriculography, pulmonary arteriography, and venography; studies of the collateral arteries and aortography, including the aortic root, aortic arch, ascending and descending aorta). Omnipaque 300 is indicated for angiocardiography (ventriculography), excretory urography, and contrast enhancement for CT head imaging. Omnipaque 240 is indicated for contrast enhancement for CT head imaging. Intrathecal: - Adults: Omnipaque 180, 240, and 300 are indicated for intrathecal administration in adults including myelography (lumbar, thoracic, cervical, total columnar) and in contrast enhancement for computerized (CT) (myelography, cisternography, ventriculography). Children: Omnipaque 180 is indicated for intrathecal administration in children including myelography (lumbar, thoracic, cervical, total columnar) and in contrast enhancement for CT (myelography, cisternography). Oral/Body Cavity Use: Adults: Omnipaque 350 is indicated for arthrography and oral pass-thru examination of the gastrointestinal (GI) tract. Omnipaque 300 is indicated for arthrography and hysterosalpingography. Omnipaque 240 is indicated for arthrography, endoscopic retrograde pancreatography and cholangiopancreatography, herniography, and hysterosalpingography. Children: Omnipaque 300 is indicated for examination of the GI tract. Omnipaque 240 is indicated for examination of the GI tract. Omnipaque 180 is indicated for examination of the GI tract. Omnipaque diluted to concentrations from 50 mgI/mL to 100 mgI/mL is indicated for voiding cystourethrography. Oral/IV Use: Oral Omnipaque diluted to concentrations from 9 mgI/mL to 21 mgI/mL administered orally in conjunction with Omnipaque 240 [pediatric] and 300 [pediatric and adult] administered intravenously is indicated for use in contrast enhanced computed tomography of the abdomen.
CONTRAINDICATIONS - Omnipaque should not be administered to patients with a known hypersensitivity to iohexol. Myelography should not be performed in the presence of significant local or systemic infection where bacteremia is likely. Intrathecal administration of corticosteroids with Omnipaque is contraindicated. Because of the possibility of overdosage, immediate repeat myelography in the event of technical failure is contraindicated.

WARNINGS: Intravascular and Oral Use: Serious, rarely fatal, thromboembolic events causing myocardial infarction and stroke have been reported during angiographic procedures with both ionic and nonionic contrast media. Omnipaque should be used with extreme care in patients with severe functional disturbances of the liver and kidneys, severe thyrotoxicosis, or myelomatosis. Diabetics with a serum creatinine level above 3 mg/dL should not be examined unless the possible benefits of the examination clearly outweigh the additional risk. Omnipaque is not recommended for use in patients with anuria. Contrast media are potentially hazardous in patients with multiple myeloma or other paraproteinemia. Ionic contrast media, when injected intravenously or intra-arterially, may promote sickling in individuals who are homozygous for sickle cell disease. Administration of contrast to patients known or suspected of having pheochromocytoma should be performed with extreme caution and the dose injected should be kept to an absolute minimum. The patient’s blood pressure should be assessed throughout the procedure and measures for the treatment of hypertensive crisis should be readily available. Reports of thyroid storm have been reported following the use of iodinated, ionic contrast media in patients with hyperthyroidism or with an autonomously functioning thyroid nodule. Urography should be performed with caution in patients with severely impaired renal function and patients with combined renal and hepatic disease. Intrathecal Use: Caution is advised in patients with a history of epilepsy, severe cardiovascular disease, chronic alcoholism, or multiple sclerosis. Elderly patients may present a greater risk following myelography. Special attention must be paid to dose and concentration of the medium, hydration, and technique used. Drugs that lower the seizure threshold, especially phenothiazine derivatives, including those used for their antihistamine properties, are not recommended for use with Omnipaque. While the contributory role of these medications has not been established, the use of such drugs should be based on physician evaluation of potential benefits and potential risks. Direct intracisternal or ventricular administration for standard radiography (not CT) is not recommended.

PRECAUTIONS-General: Patients should be well hydrated prior to and following administration of any contrast medium. The possibility of a reaction, including serious, life threatening, fatal, anaphylactoid, cardiovascular (CV) or central nervous system reactions, should always be considered. The possibility of an idiosyncratic reaction in susceptible patients should always be considered. The susceptible population includes, but is not limited to, patients with a history of a previous reaction to contrast media, patients with a known sensitivity to iodine per se, and patients with a known clinical hypersensitivity: bronchial asthma, hay fever, and food allergies. After parenteral administration of a contrast agent, competent personnel and emergency facilities should be available for at least 30 to 60 minutes since severe delayed reactions have occurred. Renal Impairment: Use in patients with hepatorenal insufficiency only if the possibility of benefit clearly outweighs the additional risk. Diabetics: Acute renal failure has been reported in diabetic patients with diabetic nephropathy and in susceptible non-diabetic patients (often elderly with preexisting renal disease) following excretory
Congestive Heart Failure (CHF): The potential transitory increase in the circulatory osmotic load in patients with CHF requires caution during injection. These patients should be observed for several hours following the procedure to detect delayed hemodynamic disturbances. General anesthesia may be indicated in the performance of some procedures in selected adult patients; however, a higher incidence of adverse reactions has been reported in these patients. Angiography should be avoided whenever possible in patients with homocystinuria, because of the risk of inducing thrombosis and embolism. Selective coronary arteriography should be performed only in those patients in whom the expected benefits outweigh the potential risk.

Repeat Procedures: If in the clinical judgment of the physician sequential or repeat examinations are required, a suitable interval of time between administrations should be observed to allow for normal clearance of the drug from the body. Nursing Mothers: It is not known to what extent iohexol is excreted in human milk. However, many injectable contrast agents are excreted unchanged in human milk. Although it has not been established that serious adverse reactions occur in nursing infants, caution should be exercised when intravascular contrast media are administered to nursing women. Bottle feedings may be substituted for breast feedings for 24 hours following administration of Omnipaque. Pediatric Use: Pediatric patients at higher risk of experiencing adverse events during contrast medium administration may include those having asthma, sensitivity to medication and/or allergens, congestive heart failure, a serum creatinine greater than 1.5 mg/dL or those less than 12 months of age.

ADVERSE REACTIONS—Intrathecal Use: The most frequently reported adverse reactions with Omnipaque are headache, mild to moderate pain including backache, neck ache and stiffness, nausea, and vomiting. These reactions usually occur 1 to 10 hours after injection, and almost all occur within 24 hours. Rarely, headaches may be severe or persist for days. Transient alterations in vital signs may occur and their significance must be assessed on an individual basis. Oral Use is associated with mild transient, transient diarrhea, especially following high concentrations and volumes, which may result in hypovolemia. Plasma fluid loss may be sufficient to cause a shock-like state that, if untreated, could be dangerous, especially in elderly, cachectic patients of any age and infants and small children. General Reactions to Contrast Media: Serious, life-threatening and fatal reactions, mostly of CV origin, have been associated with the administration of all iodine-containing contrast media. Aseptic meningitis syndrome has been reported rarely. Profound mental disturbances have been reported rarely, usually consisting of various forms and degrees of aphasia, mental confusion, or disorientation. The onset is usually at 8 to 10 hours and lasts for about 24 hours, without after effects. Rarely, persistent though transitory weakness in the leg or ocular muscles has been reported. Peripheral neuropathies have been rare and transitory. In general, the reactions, which are known to occur upon parenteral administration of iodinated contrast agents, are possible with any nonionic agent. The reported incidence of adverse reactions to contrast media in patients with a history of allergy is twice that of the general population. Patients with a history of previous reactions to a contrast medium are three times more susceptible than other patients. Most adverse reactions to injectable contrast media appear within 1 to 3 minutes after the start of injection, but delayed reactions may occur. The injection of contrast media is frequently associated with the sensation of warmth and pain, especially in peripheral angiography.

Prior to Omnipaque administration, please read the Full Prescribing Information.