Packaging of Pharmacologic Stress Agents: Hospital Outpatient Departments (HOPDs) no longer receive separate payment for pharmacologic stress agents as of 2014. For dates of service on or after January 1, 2014, pharmacologic stress agents are packaged into the myocardial perfusion imaging (MPI) procedure and are no longer separately reimbursed by Medicare. However, it remains important to continue coding for all products and services provided to the patient.

The 2016 Medicare packaged hospital Outpatient Prospective Payment System (OPPS) payment rate for SPECT myocardial perfusion imaging (MPI) procedures will be $1108.46. This payment is based on historical claims data from 2014 and includes the following items and services if provided:

- the nuclear medicine imaging procedure (eg, 78452)
- the stress test (ie, 93017)
- the pharmacologic stress agent (eg, J2785, Lexiscan® (regadenoson) injection)

This amount will be the payment rate until 2017 at which time the rate will be reset based on historical claims data from 2015.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description</th>
<th>1Q 2016 Medicare Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Hospital Outpatient APC</td>
</tr>
<tr>
<td>78451</td>
<td>Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)</td>
<td>5593</td>
</tr>
<tr>
<td>78452</td>
<td>Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection</td>
<td>5593</td>
</tr>
<tr>
<td>78453</td>
<td>Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)</td>
<td>5592</td>
</tr>
<tr>
<td>78454</td>
<td>Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection</td>
<td>5593</td>
</tr>
</tbody>
</table>

Effect of Sequestration: For the items and services shown here, the Medicare program pays 80% of the payment amount and the beneficiary is responsible for the remaining 20%. Effective April 1, 2013, the Medicare program payment is reduced by 2% because of the sequester required by the Budget Control Act of 2011. The beneficiary portion of the payment is not affected by the sequester. As a result of the sequester, the total payment to the physician or hospital is reduced 1.6%. For example, without the sequester, the payment for 78452 would be $1108.46, of which the program would pay $886.77 and the beneficiary would pay $221.69. With the sequester, the program pays $869.03, the beneficiary still pays $221.69, and the total payment to the hospital is $1090.72. The sequester affects all fee-for-service program payments, including those for physician services, hospital outpatient department services, drugs, and dispensing and supplying fees.³

PLEASE SEE INDICATION AND IMPORTANT SAFETY INFORMATION. PLEASE SEE FULL PRESCRIBING INFORMATION HERE OR PROVIDED BY YOUR ASTELLAS REPRESENTATIVE.
Medicare’s reimbursement mechanism for Lexiscan varies according to the setting of care. Lexiscan may be paid separately when provided in sites of service other than the hospital inpatient or outpatient setting. Including the effect of sequestration, the total payment to physicians is ASP + 4.3% for separately covered outpatient drugs.

Although hospital outpatient facilities will not receive a separate payment for pharmacologic stress agents in 2016, the cost of the product is still factored into the packaged payment amount on an annual basis. CMS determines the payment rate based on costs calculated from hospital claims. Therefore you should continue to enter the HCPCS code for Lexiscan when billing to be sure that the costs for the product are reported to Medicare and included in the calculation of the MPI payment rate. In a 2010 transmittal, CMS stated that “...hospitals are strongly encouraged to report charges for all drugs, biologicals and radiopharmaceuticals regardless of whether the items are paid separately or packaged, using the correct HCPCS codes for the items used.”

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<th>CPT Codes</th>
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</tr>
</thead>
<tbody>
<tr>
<td>93017</td>
<td>Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; tracing only, without interpretation or report</td>
<td>Packaged when performed with MPI</td>
</tr>
</tbody>
</table>

Lexiscan is supplied as a standard-dose prefilled syringe: Injection solution containing regadenoson 0.4 mg/5 mL (0.08 mg/mL). To report 0.4 mg, or standard-dose prefilled syringe, it is important to code for “4” units.

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Lexiscan® (regadenoson) injection

INDICATION
Lexiscan is a pharmacologic stress agent indicated for radionuclide myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress.

IMPORTANT SAFETY INFORMATION

CONTRAINdications
Do not administer Lexiscan to patients with second- or third-degree AV block or sinus node dysfunction unless these patients have a functioning artificial pacemaker.

WARNINGS AND PRECAUTIONS

Myocardial Ischemia
Fatal and nonfatal myocardial infarction, ventricular arrhythmias, and cardiac arrest have occurred following Lexiscan injection. Avoid use in patients with symptoms or signs of acute myocardial ischemia, for example unstable angina or cardiovascular instability; these patients may be at greater risk of serious cardiovascular reactions to Lexiscan. Cardiac resuscitation equipment and trained staff should be available before administering Lexiscan. If serious reactions to Lexiscan occur, consider the use of aminophylline, an adenosine antagonist, to shorten the duration of increased coronary blood flow induced by Lexiscan.

Sinoatrial and Atrophicventricular Nodal Block
Adenosine receptor agonists, including Lexiscan, can depress the SA and AV nodes and may cause first-, second-, or third-degree AV block, or sinus bradycardia requiring intervention. In postmarketing experience, heart block (including third degree), and asystole within minutes of Lexiscan administration have occurred.

Atrial Fibrillation/Atrial Flutter
New-onset or recurrent atrial fibrillation with rapid ventricular response and atrial flutter have been reported following Lexiscan injection.

Hypersensitivity, Including Anaphylaxis
Anaphylaxis, angioedema, cardiac or respiratory arrest, respiratory distress, decreased oxygen saturation, hypotension, throat tightness, urticaria and rashes have occurred. In clinical trials, hypersensitivity reactions were reported in fewer than 1 percent of patients.

Hypotension
Adenosine receptor agonists, including Lexiscan, induce arterial vasodilation and hypotension. The risk of serious hypotension may be higher in patients with autonomic dysfunction, hypovolemia, left main coronary artery stenosis, senile valvar heart disease, pericarditis or pericardial effusions, or stenotic carotid artery disease with cerebrovascular insufficiency. In postmarketing experience, transient ischemic attacks, seizures, and syncope have been observed.

Hypertension
Adenosine receptor agonists, including Lexiscan, may result in clinically significant increases in blood pressure in some patients. In postmarketing experience, cases of potentially clinically significant hypertension have been reported, particularly in patients with underlying hypertension and when low-level exercise was included in the MPI.

Bronchocstriction
Adenosine receptor agonists, including Lexiscan, may cause dyspnea, bronchoconstriction and respiratory compromise. Appropriate bronchodilator therapy and resuscitative measures should be available prior to Lexiscan administration.

Seizure
Lexiscan may lower the seizure threshold. New-onset or recurrence of convulsive seizures has occurred following Lexiscan injection. Some seizures are prolonged and require emergent anticonvulsive management. Aminophylline may increase the risk of seizures associated with Lexiscan injection. Methylxanthine use is not recommended in patients who experience a seizure in association with Lexiscan administration.

Cerebrovascular Accident (Stroke)
Hemorrhagic and ischemic cerebrovascular accidents have occurred. Hemodynamic effects of Lexiscan including hypotension or hypertension may be associated with these adverse reactions.

ADVERSE REACTIONS

In clinical trials, the most common adverse reactions (≥5%) to Lexiscan were dyspnea, headache, flushing, chest discomfort, angina pectoris or ST-segment depression, dizziness, chest pain, nausea, abdominal discomfort, dysgeusia, and feeling hot. Most adverse reactions began soon after dosing, and generally resolved within approximately 15 minutes, except for headache, which resolved in most patients within 30 minutes. Aminophylline was used as a reversal agent in 3% of patients.

In postmarketing experience, the following additional adverse reactions have occurred: supraventricular tachycardias, tremor, QTc prolongation, abdominal pain in association with nausea, vomiting, or myalgias, diarrhea, fecal incontinence, wheezing and musculoskeletal pain.

IMPORTANT INFORMATION: The coding, coverage, and payment information contained herein is gathered from various resources, general in nature, and subject to change without notice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider’s responsibility to determine the appropriate healthcare setting and to submit true and correct claims conforming to the requirements of the relevant payer for those products and services rendered. Pharmacies (or any other provider submitting a claim) should contact third-party payers for specific information on their coding, coverage, and payment policies. Information and materials provided by Astellas Pharma Support Solutions are to assist pharmacies, but the responsibility to determine coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains at all times with the pharmacy and information provided by Astellas Pharma Support Solutions or Astellas should in no way be considered a guarantee of coverage or reimbursement for any product or service.

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