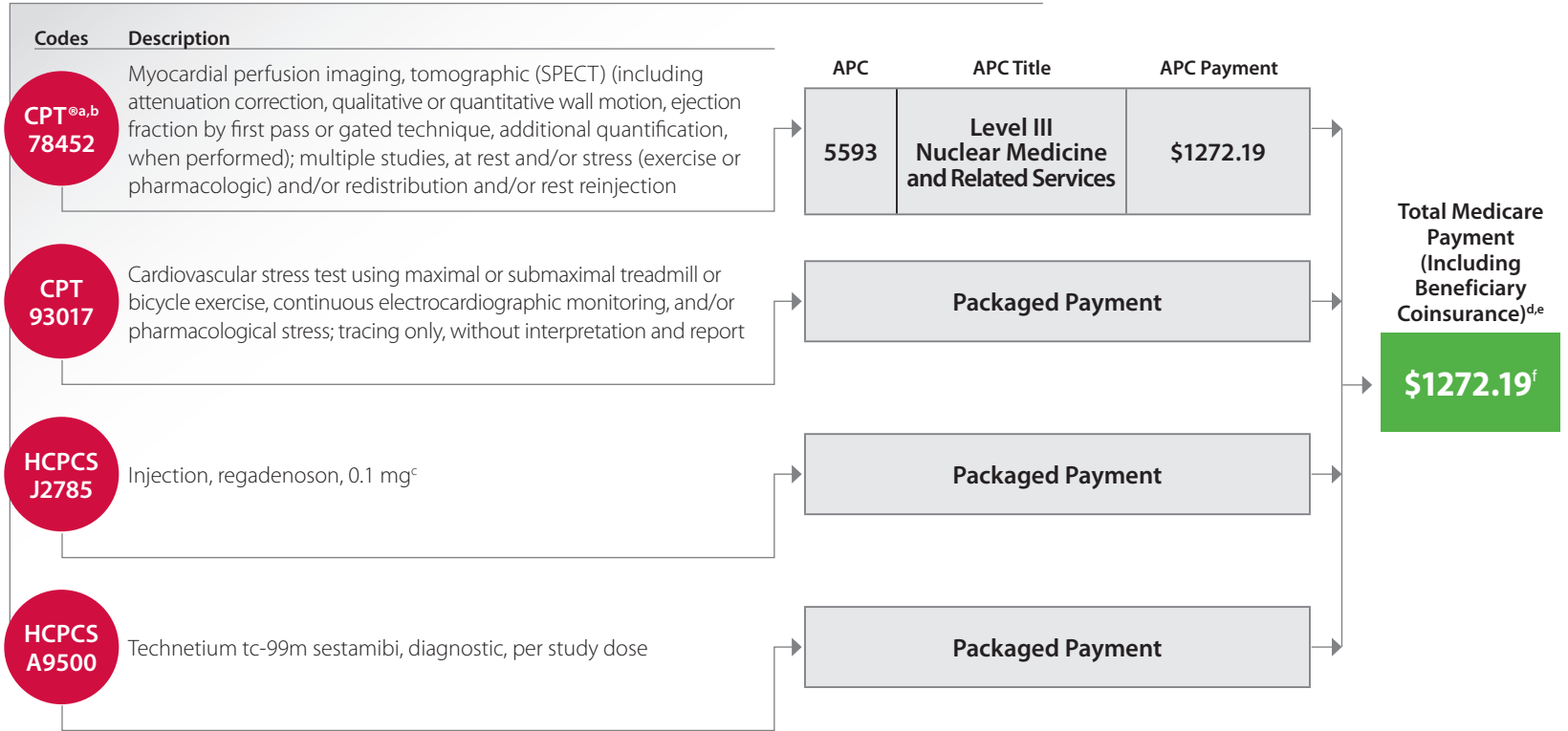


Lexiscan® (regadenoson) injection is part of the package

The cost of pharmacologic stress agents is accounted for in the packaged payment for nuclear medicine imaging procedures, along with the cost of other items and services associated with the imaging procedure, such as a stress test and diagnostic radiopharmaceuticals.¹

2020 HOPPS Billing and Payment Example for Lexiscan²⁻⁵



CPT = Current Procedural Terminology; HCPCS = Healthcare Common Procedure Coding System; HOPPS = Hospital Outpatient Prospective Payment System.

^aAmerican Medical Association. Current Procedural Terminology (CPT). Professional edition, 2020. All rights reserved. Applicable FARS/DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMS, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

^bCPT codes 78451, 78452, 78453, and 78454 are assigned to APC 5593.

^cLexiscan 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**.

^dSource: 2020 CMS HOPPS addendum B updates.

^eBecause Lexiscan is packaged, the payment adjustment applied to separately payable drugs obtained under the 340B program does not affect payment for Lexiscan. Hospitals may report the modifiers that indicate whether or not a drug is acquired through the 340B program with the Lexiscan codes, but are not required to use the modifiers.⁶

^fFigure does not reflect the impact of sequestration, which reduces the Medicare portion of the payment amounts by 2% but does not reduce the applicable beneficiary cost sharing. In response to COVID-19, Congress has suspended the impact of sequestration on Medicare payments for the period between May 1, 2020, and December 31, 2020.⁷

THE PAYMENT RATES IN THIS DOCUMENT REFLECT NATIONAL AVERAGE PAYMENT AMOUNTS. THE ACTUAL PAYMENT TO A HOSPITAL WILL VARY WITH THE APPLICATION OF AN ADJUSTMENT TO REFLECT GEOGRAPHIC VARIATION IN LABOR COSTS. OTHER ADJUSTMENTS MAY ALSO APPLY FOR HIGH-COST CASES OR FOR SERVICES PROVIDED BY CERTAIN TYPES OF HOSPITALS SUCH AS CANCER HOSPITALS.

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. This coding and billing information is provided 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 should in no way be considered a guarantee of coverage or reimbursement for any product or service.

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.

**PLEASE SEE ADDITIONAL IMPORTANT SAFETY INFORMATION.
PLEASE SEE FULL PRESCRIBING INFORMATION [HERE](#).**

INDICATION

Lexiscan® (regadenoson) injection 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. Adhere to the recommended duration of injection. As noted in an animal study, longer injection times may increase the duration and magnitude of increase in coronary blood flow. 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 Atrioventricular 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, stenotic valvular 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.

Bronchoconstriction

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

Seizure

Lexiscan may lower the seizure threshold; obtain a seizure history. 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 ($\geq 5\%$) 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 tachyarrhythmias, acute coronary syndrome (ACS), tremor, QTc prolongation, abdominal pain in association with nausea, vomiting, or myalgias, diarrhea, fecal incontinence, wheezing and musculoskeletal pain.

PLEASE SEE FULL PRESCRIBING INFORMATION [HERE](#).

REFERENCES

- Centers for Medicare & Medicaid Services. Medicare program: hospital outpatient prospective payment systems and ambulatory surgical center payment systems and quality reporting programs; hospital value-based purchasing program; organ procurement organizations; quality improvement organizations; Electronic Health Records (EHR) Incentive Program; provider reimbursement determinations and appeals. Fed Regist 2013;78(237):74826-5200. **2.** American Medical Association. CPT® 2020 Professional Edition. Chicago, IL: American Medical Association; 2019. **3.** Centers for Medicare & Medicaid Services. ASP drug pricing files January 2020 update (12-02-2019). www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2020-asp-drug-pricing-files. Accessed 01-30-2020. **4.** American College of Radiology. Calendar year 2020 hospital outpatient prospective payment system final rule (11-13-2019). www.acr.org/Advocacy-and-Economics/Advocacy-News/Advocacy-News-Issues/In-the-November-16-2019-Issue/2020-HOPPS-Final-Rule. Accessed 01-30-2020. **5.** Centers for Medicare & Medicaid Services. Hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs. www.cms.gov/medicare/medicare-fee-service-payment/hospitaloutpatientppsaddendum-and-addendum-b-updates/january-2020-0. Accessed 01-30-2020. **6.** Centers for Medicare & Medicaid Services. FFS Program Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (HOPPS) (04-02-2018). www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Billing-340B-Modifiers-under-Hospital-OPPS.pdf. Accessed 01-30-2020. **7.** Coronavirus Aid, Relief, and Economic Security Act, HR 748, 116th Cong, 2nd Sess (2020).



Lexiscan® is a registered trademark of Astellas US LLC. Lexiscan Support SolutionsSM, a component of Astellas Pharma Support SolutionsSM, is a service mark of Astellas Pharma US, Inc. All other trademarks or registered trademarks are the property of their respective owners.

Lexiscan was developed in collaboration with Gilead Palo Alto, Inc. (formerly CV Therapeutics, Inc.).

©2020 Astellas Pharma US, Inc. All rights reserved. 012-1512-PM 5/20